

ESTTA Tracking number: **ESTTA594064**

Filing date: **03/22/2014**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91206915
Party	Defendant Eric Lucas
Correspondence Address	DAMON L WARD WARD LAW GROUP 301 4TH AVE S STE 378N MINNEAPOLIS, MN 55415 1015 UNITED STATES dward@wardlawgroup.com
Submission	Opposition/Response to Motion
Filer's Name	Damon L. Ward
Filer's e-mail	dward@wardlawgroup.com
Signature	/Damon L. Ward/
Date	03/22/2014
Attachments	TTAB Opposition Response Submission.pdf(4364061 bytes)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

In the matter of Application Serial No.: 85/597,114
Published in the Official Gazette on August 28, 2012

MYBODY, L.L.C.,

Opposer,
vs.

ERIC LUCAS,

Applicant.

Opposition No. 91206915

Memorandum in Opposition to Opposer's
Motion for Summary Judgment

Applicant submits this memorandum in opposition to Opposer's Motion for Summary Judgment.

INTRODUCTION

Opposer's characterizations of the grounds on which it maintains it is entitled to summary judgment are misleading and self-serving. Opposer seeks Summary Judgment that Applicant's applied-for mark (Serial No. 85/597,114) MY HERO for lotion is confusingly similar to Opposer's pink colored logo "myHERO" for an anti-aging serum which Opposer deceptively (and solely for purposes of this opposition) has now identified as a skin cream after the United States Patent and Trademark Office refused registration of the logo and after Applicant applied for federal registration of his mark. Opposer's Motion must be denied because there are material issues of fact as to whether Opposer has established priority of use, whether there is a likelihood of confusion between Applicant's MYHERO mark and Opposer's pink colored myHERO logo, and whether Opposer's anti-aging serum is really a medicinal treatment according to FDA standards requiring it to be re-classified for purposes of determining the true market differences between the products at issue, the actual target consumer, and the consumer sophistication. Notably, Opposer's memorandum of law fails to properly address, and in most cases, fails to address at all, these material questions fact. Instead, Opposer has elected to set forth bald statements as evidence and in doing so fails to carry its stringent burden on its motion.

Indeed, throughout its memorandum, Opposer habitually ignores inconvenient facts, such as its own conflicting arguments it raised in response to previous Office Actions, the nature of its medicinal anti-aging serum (now curiously referred to as a skin cream), the self-described targeting of the anti-aging serum to a limited marketing channel and consumer, and the readily-apparent difference in consumer impression between the marks themselves. Given the multiple deficiencies in its arguments and the lack of evidentiary proofs, it is clear that Opposer has not presented the clear and convincing evidence required to overcome its evidentiary hurdle on summary judgment.

Applicant's motion opposition, however, does not rest solely on the fact that Opposer has not demonstrated the required lack of genuine issues of fact for trial. Applicant not only provides the applicable standard (which Opposer failed to set forth or demonstrate), but also provides this tribunal with information from Opposer's own discovery responses as well as its own submissions to the USPTO from its original failed attempt to register the logo that is more than sufficient to defeat summary judgment.

In light of Opposer's deficient submissions and Applicant's proofs, Opposer's motion must be denied.

BACKGROUND AND PROCEDURAL POSTURE

On April 13, 2012, Eric Lucas ("Applicant"), filed to register the mark "MYHERO" based upon a bona fide intent to use the mark in commerce. Declaration of Damon L. Ward, Exhibit 1 (Application). On August 8, 2012, Applicant received notice that the USPTO determined that Applicant's mark appeared entitled to registration. Ward Decl., Exhibit 2 (Notice of Publication).

On September 10, 2012, Opposer initiated this proceeding in an effort to prevent Applicant from completing the trademark application process *after* the United States Patent and Trademark Office refused registration of MYHERO for Opposer's anti-aging serum and *after* Applicant received Publication Confirmation in the Official Gazette subsequent to a determination that Applicant's mark may be registered. See Opposition, Exhibit 3 (Refusal re: Opposer's serial # 85132776).

On February 20, 2014, Opposer brought its motion for summary judgment. In support of its motion on the inextricably intertwined alleged grounds of priority and likelihood of confusion, however,

Opposer submits only the following broad and conclusory statements said to be supported by generalized and non-specific discovery responses:

1. My Body LLC is an Arizona limited liability company with a business address at 5080 North 40th Street, Suite 375, Phoenix, Arizona 85018 (“Opposer”), operates a business that develops and markets skin care and related products. . . .
2. As of January 28, 2011, Opposer adopted and has continually and extensively used the mark “MYHERO” in connection with the sale of its skin cream products since that date. . . .
3. Opposer has expended considerable time and resources to advertise and promote the skin cream products offered under its “MYHERO” mark. . . .
4. Opposer has identified channels of trade where Opposer’s goods have been sold, are sold, and intend to be sold as: medical offices, spas, beauty spas, department stores, specialty stores, online retailers, consumer sales, and via its website

Opposer’s Statement of Material Facts, pp. 1-2.

However, Opposer fails to identify that (1) Opposer has never marketed, promoted, or sold its product as a “skin cream,” rather only doing so as an anti-aging serum; Ward Decl., Exhibit 4 (Advertising) (2) Opposer has improperly identified the anti-aging serum in International Class 003 when, as a medicinal product pursuant to FDA regulations, it should be classified in International Class 005 as a drug Ward Decl., Exhibit 5 (Opposer’s application for anti-aging serum); (3) Opposer’s product contains retinol and contains statements demonstrating it is a drug Ward Decl., Exhibit 6 (Ingredient Advertising); Exhibit 7 (FDA Compliance & Regulatory Information), and Exhibit 8 (Warning Letters); (4) Opposer represented to USPTO that the anti-aging serum was target marketed to the aging and mature women Ward Decl., Exhibit 9 (Opposer’s Response to Office action); (5) Opposer has never used the myHERO logo on any identified cosmetic skin creams, only its anti-aging serum, and only first claimed to be using it for “skin creams” in Opposer’s most recent Application dated August 6, 2012--14 months *after* its anti-aging serum application was refused registration and abandoned and four months *after* Applicant made its application.

ARGUMENT

I. STANDARD FOR SUMMARY JUDGMENT

Summary judgment is proper if, drawing all reasonable inferences in favor of the nonmoving party, there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a); Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986). The moving party bears the burden of showing that the material facts in the case are undisputed. Id. at 322; Whisenhunt v. Sw. Bell Tel., 573 F.3d 565, 568 (8th Cir. 2009). The Board must view the evidence, and the inferences that may be reasonably drawn from it, in the light most favorable to the nonmoving party. Weitz Co., LLC v. Lloyd's of London, 574 F.3d 885, 892 (8th Cir. 2009); Carraher v. Target Corp., 503 F.3d 714, 716 (8th Cir. 2007); See Capital Speakers Inc. v. Capital Speakers Club of Washington D.C. Inc., 41 U.S.P.Q.2d 1030, 1034 (TTAB 1996) (Board accepted nonmovant's version of the facts for purposes of deciding motion); Commodore Electronics Ltd., 26 U.S.P.Q.2d at 1505 (on opposer's motion for summary judgment applicant's evidence of statement of use filed in connection with another of its applications covering many of same goods as in opposed application created inference of bona fide intent to use present mark despite absence of any documents regarding its intent to use present mark). See also Opryland USA Inc. v. The Great American Music Show Inc., 23 U.S.P.Q.2d 1471, 1472 (Fed. Cir. 1992) (not required to present entire case but just sufficient evidence to show an evidentiary conflict as to the material fact in dispute). A factual dispute is genuine if sufficient evidence is presented such that a reasonable fact finder could decide the question in favor of the non-moving party. Sweats Fashions Inc. v. Pannill Knitting Co., 4 U.S.P.Q.2d 1793, 1795 (Fed. Cir. 1987). The burden resting on the non-moving party is to show that specific facts exist creating a genuine issue for trial. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256 (1986); Wingate v. Gage County Sch. Dist. No. 34, 528 F.3d 1074, 1078-79 (8th Cir. 2008).

Summary judgment is a drastic remedy and the Board is only to resolve any doubts as to the existence of genuine issues of fact against the moving party. Enter. Bank v. Magna Bank of Mo.,

92 F.3d 743, 747 (8th Cir.1996). The Board's function is not to weigh the evidence and determine the truth of the matter, but to determine whether there is a genuine issue for trial. See Anderson, 477 U.S. at 249. The Board does not resolve issues of fact on summary judgment. See Dyneer Corp. v. Automotive Products plc, 37 U.S.P.Q. 1251, 1254 (TTAB 1995); Meyers v. Brooks Shoe Inc., 912 F.2d 1459, 1461, 16 U.S.P.Q.2d 1055, 1056 (Fed. Cir. 1990), overruled on other grounds by A.C. Aukerman Co. v. R.L. Chaides Constr. Co., 960 F.2d 1020, 1038-39, 22 U.S.P.Q.2d 1321, 1333 (Fed. Cir. 1992).

Indeed, the nonmoving party is entitled to the benefit of all reasonable inferences to be drawn from the underlying facts in the record, and the Board must view the evidence and those inferences in the light most favorable to the nonmoving party. See Lloyd's Food Prods. Inc. v. Eli's Inc., 987 F.2d 766, 767, 25 U.S.P.Q.2d 2027, 2029 (Fed. Cir. 1993); Opryland USA Inc. v. Great Am. Music Show Inc., 970 F.2d 847, 850, 23 U.S.P.Q.2d 1471, 1472 (Fed. Cir. 1992); Vette Co. v. Aetna Casualty & Surety Co., 612 F.2d 1076, 1077 (8th Cir.1980); Enter. Bank v. Magna Bank of Mo., 92 F.3d 743, 747 (8th Cir.1996). As long as there appears to be some support for the disputed allegations such that “reasonable minds could differ as to the import of the evidence,” the motion must be denied. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250 (1986).

Moreover, credibility of testimony cannot be resolved on a motion for summary judgment, as credibility is an issue to be determined by the fact-finder. Tiemann v. Ind. School Dist. No. 740, 331 N.W.2d 250, 251 (Minn. 1983). Summary judgment should not be granted if reasonable persons might reach different conclusions after reviewing the evidence. Basically, summary judgment is only appropriate when “there is no dispute of fact and where there exists only one conclusion.” Crawford v. Runyon, 37 F.3d 1338, 1341 (8th Cir.1994).

The Board employs a two-part test to determine whether there are genuine issues of material fact. The materiality of a fact is determined from the substantive law governing the claim. Only disputes over facts that impact the outcome of the case are considered material for purposes of

summary judgment. Anderson, 477 U.S. at 252; Planned Parenthood of Minnesota/South Dakota v. Rounds, 372 F.3d 969, 972 (8th Cir. 2004). The dispute over material facts must be genuine. A dispute is genuine if the evidence is such that it could cause a reasonable fact-finder to return a determination for either party. Id.

Opposer, as the party moving for summary judgment, has the burden of demonstrating the absence of any genuine issue of material fact. See Celotex Corp. v. Catrett, 477 U.S. at 322-37. To prevail on its motion, Opposer must establish that there is no genuine issue of fact regarding the issues at hand by clear and convincing evidence. See H. Marvin Ginn Corp. v. Int'l Ass'n of Fire Chiefs, Inc., 782 F.2d 987, 989-90, 228 U.S.P.Q. 528, 530 (Fed. Cir. 1986). Opposer is held to a “stringent standard,” for summary judgment. Summary judgment is “not a substitute for the trial of disputed issues of fact.” Walters Gardens, Inc. v. Pride Of Place Plants, Inc., Opp’n No. 91153755, 2004 WL 1149499, at *6 (T.T.A.B. May 4, 2004) (nonprecedential). Moreover, “[a]ll doubts as to whether or not particular factual issues are genuinely in dispute must be resolved against the moving party.” Flatley v. Trump, 11 USPQ2d 1284, 1287 (TTAB 1989).

For his part, in order to have the opportunity to submit proofs at trial, Applicant need only show that, on the evidence of record, a reasonable fact finder could resolve the matter in his favor. See Opreyland USA Inc. v. Great Am. Music Show Inc., 970 F.2d 847, 850, 23 U.S.P.Q.2d 1471, 1472-73 (Fed. Cir. 1992); Olde Tyme Foods Inc. v. Roundy’s Inc., 961 F.2d 200, 202, 22 U.S.P.Q.2d 1542, 1544 (Fed. Cir. 1992); see also Visa Int’l Serv. Ass’n v. Life-Code Sys., Inc., 220 U.S.P.Q. 740, 742 (T.T.A.B. 1983) (on a summary judgment motion, “nonmoving party is not required to adduce evidence sufficient to prove its case . . . ”; it need only show “that there is a genuine issue as to a material fact and that, therefore, there is a need for a trial”).

In the light most favorable to Applicant as the nonmoving party, Opposer’s assertions must fail and its motion must be denied in its entirety.

II. STATEMENT OF DISPUTED FACTUAL ISSUES FOR TRIAL

- A. Whether Opposer Has Established Priority of Use.**
- B. Whether Opposer Has Established Priority of Nationwide Use Beyond Its Geographic Location Sufficient to Prevent Federal Registration.**
- C. Whether There Is A Likelihood Of Confusion In View Of (1) The Dissimilarity of The MY HERO Mark And Opposer's myHERO Logo; (2) The Dissimilarity Of Product Between Applicant's Lotion and Opposer's Anti-Aging Serum; (3) Opposer's Targeted Marketing of Aging/Wrinkled Adult Women; (4) The Differing Commercial Impression Between Opposer's "myHERO" Logo And Applicant's "MY HERO" Mark; and (4) The Sophistication of The Targeted Consumer for Personal Anti-Aging Serums.**
- D. Whether Opposer's Product, More Properly Classified as a Medication Pursuant to the Food and Drug Administration Standards, was Misclassified in Opposer's 2010 Trademark Application and Opposer's 2012 Application.**

While Opposer has presented *its side* of the disputed issues, its attempt to carry its burden of establishing that no genuine issues exist for trial falls substantially short of clear and convincing evidence of no genuine issue of material fact. Indeed, Opposer's own marketing conduct and previous filings with the USPTO contradict and undermine its woefully deficient argument. Genuine issues of material fact remain extant and should proceed to trial.

III. OPPOSER IS NOT ENTITLED TO SUMMARY JUDGMENT ON THE ISSUE OF PRIORITY

Contrary to the severely limited pleading submission of Opposer, much more is required of the logo holder to establish priority of trademark rights sufficient to prevent the federal registration of Applicant's mark. Because neither Applicant's mark nor Opposer's logo has yet been federally registered, the issue is whether priority has been established by Opposer under common law to support its bid for summary judgment. Despite Opposer's talismanic conclusion that Opposer has "indisputable prior proprietary rights in the mark," its conclusion and absolute anemic discussion of the law is simply oversimplified and wrong.

- A. Opposer Has Not Established Priority of Use.**

Contrary to Opposer's gossamer thin explanation of its thoughts on priority, to establish priority,

Opposer must do more than just show a proprietary interest in the mark. Opposer must demonstrate “proprietary rights in the mark *that produce a likelihood of confusion.*” Herbko, Int’l, Int’l. Inc. v. Kappa Books Inc., 308 F.3d 1156 (Fed Cir. 2002), citing, Otto Roth & Co. v. Universal Foods Corp., 640 F.2d 1317, 1320, 209 USPQ 40, 43 (CCPA 1981). Before a prior use becomes an analogous use sufficient to create proprietary rights, Opposer must show prior use *sufficient to create an association in the minds of the purchasing public between the mark and Opposer’s goods.* Malcolm Nicol & Co. v. Witco Corp., 881 F.2d 1063, 1065, 11 USPQ2d 1638, 1639 (Fed. Cir. 1989). The activities claimed to create such an association must reasonably be expected to have a substantial impact on the purchasing public before a later user acquires proprietary rights in a mark. Id.

Moreover, to establish that it has proprietary rights in the mark, Opposer must establish that MYHERO “is distinctive of its so-called skin cream either inherently or through the acquisition of secondary meaning.” Hoover Co. v. Royal Appliance Manufacturing Co., 238 F.3d 1357, 57 USPQ2d 1720, 1721 (Fed. Cir. 2001); Otto Roth & Co., Inc. v. Universal Foods Corp., 640 F.2d 1317, 209 USPQ 40, 44 (CCPA 1981) (discussing requirements of inherent distinctiveness).

Notwithstanding this precedent, conspicuously absent from Opposer’s memorandum of law are both the proper legal standard to establish priority and any cogent evidence sufficiently establishing its so-called “indisputable” prior proprietary rights. Not only has Opposer utterly failed to provide any analysis of what is necessary to establish an association in the minds of the purchasing public, it has failed to supply any *evidence* of prior use sufficient to create an association in the minds of the purchasing public between the mark and Opposer’s goods. Therefore, Opposer has failed to carry its burden on this motion, and its request for summary judgment must fail.

Assuming arguendo that Opposer had or could produce some semblance of evidence tending to show some association in the minds of the purchasing public (which Applicant does not concede), genuine issues of material fact still remain regarding both the alleged existence of any association, and the sufficiency thereof, if any association existed.

Indeed, Opposer is fully aware that such an association does not exist. It was determined by the

USPTO in its Office Action of June 13, 2011 refusing registration of Opposer's mark for the anti-aging serum it now conveniently refers to as a "skin cream" that, in fact, consumers would be reminded of another registrant that held the mark "HERO." Ward Decl., Exhibit 9. The examining attorney further provided evidence supporting the refusal including, but not limited to:

- Evidence from www.amazon.com offering "Swisa Dead Sea Mineral Skin Care Men's Moisturizing After Shave Balm and Skin Balancing Serum" which shows that after shave and serum are sold together and by the same entity
- Evidence showing that the manufacturer "ilike organic skin care" offers both after shave as well as anti-aging serum
- Evidence from Beauty Orchid demonstrating that anti-aging serum products and cologne travel in the same channels of trade
- Evidence from Kiehl's offering entire categories of anti-aging products and shaving products
- Evidence from <http://www.neutrogena.com/> showing that anti-aging serum products and cologne and after shave originate from the same source under the same name.

Id.

Moreover, in the absence of inherent distinctiveness, Opposer bears the burden of proving acquired distinctiveness, i.e., "secondary meaning," by a preponderance of the evidence. Tone Brothers Inc. v. Sysco Corp., 28 F.3d 1192, 31 USPQ2d 1321, 1327 (Fed. Cir. 1994) citing Yamaha Int'l Corp., 840 F.2d 1572, 6 USPQ2d at 1006, and must establish acquired distinctiveness before the date on which Applicant can establish their rights. Threshold.TV, 96 USPQ2d at 1036 and Herbko, 308 F.3d 1162, 64 USPQ2d at 1378.

Acquired distinctiveness can be shown by direct evidence such as actual testimony, declarations or surveys of consumers as to their state of mind; and/or circumstantial evidence from which consumer association might be inferred. In re Steelbuilding.com, 415 F.3d 1293, 1300, 75 USPQ2d 1420, 1424 (Fed. Cir. 2005); Threshold.TV, 96 USPQ2d at 1038; In re Brouwerij Bosteels, 96 USPQ2d 1414, 1424 (TTAB 2010). The amount and character of evidence required to establish acquired distinctiveness depends on the facts of the case and particularly on the nature of the mark sought to be registered or protected. See Roux Laboratories, Inc. v. Clairol Inc., 427 F.2d 823, 829, 166 USPQ 34, 39 (CCPA 1970). Finally, Opposer must show that the mark has acquired distinctiveness independent and separate from any other indicia on the products bearing the mark.

Here again, Opposer has provided no evidence showing consumer association. Moreover, Opposer has failed to demonstrate in any manner whatsoever that the myHERO logo creates a commercial impression distinct from any accompanying packaging or design. In failing to do so, Opposer's motion must fail. Conversely, Applicant submits that any commercial impression, if any, arises from Opposer's use of the combined pink heart/mybody design and mark (serial # 85210784 attached to Opposer's Statement of Facts, Exh. A) with the myHERO logo on its packaging and advertising. In view of the lack of evidence regarding commercial impression or consumer association and recognition of the significant role of its own company identifying indicia, the Board must conclude that to the extent any association at all exists, it is predicated upon the impression conveyed by Opposer's company name and design indicia appearing thereon rather than by any distinctive character or use of the myHERO logo.

Finally, even if Opposer properly argued the legal standard and proffered evidence of some sort of association in the minds of the purchasing public or distinctiveness (which Applicant does not concede), determination of the sufficiency of the evidence is a fact question for the fact-finder. The Board's function is not to weigh the evidence and determine the truth of the matter, but only to determine whether there is a genuine issue for trial. See Anderson, 477 U.S. at 249. The Board cannot resolve this issue of fact on summary judgment. See Dyneer Corp. v. Automotive Products plc, 37 U.S.P.Q. 1251, 1254 (TTAB 1995); Meyers v. Brooks Shoe Inc., 912 F.2d 1459, 1461, 16 U.S.P.Q.2d 1055, 1056 (Fed. Cir. 1990), overruled on other grounds by A.C. Aukerman Co. v. R.L. Chaides Constr. Co., 960 F.2d 1020, 1038-39, 22 U.S.P.Q.2d 1321, 1333 (Fed. Cir. 1992).

Accordingly, in the absence of both the legal authority and any supportable facts applied to the applicable standard, Opposer's motion must fail.

B. Even Assuming Arguendo Opposer Has Priority of Use of its myHERO Logo, Opposer Has not Established Nationwide Priority of Use Sufficient to Prohibit Applicant's Registration of MY HERO.

Like all its other arguments, Opposer has failed to argue, establish, or provide evidence supporting nationwide priority of use. The matter does not involve a dispute over two federally

registered marks or between one registered mark and one un-registered mark. This proceeding involves Applicant's prosecution of his mark MY HERO and Opposer's unregistered logo. Thus, common law principles regarding geographic concurrent use govern determination of the scope of any priority (which Applicant does not concede exists) of Opposer's unregistered logo. See Hanover Star Milling Co. v. Metcalf, 240 U.S. 403 (1916).

The U.S. Supreme Court, in Hanover Star Milling Co. v. Metcalf, outlined the common law doctrine of geographic concurrent use that is still the basis for common law concurrent use rights in trademarks. In that case, the Court refused to enjoin a junior user of the "Tea Rose" mark, rejecting a common law "first in time" property right for trademarks that would have accorded exclusive nationwide rights in a mark to the first user anywhere in the nation. Hanover Star Milling Co., 240 U.S. at 415 (distinguishing prior case language that suggested exclusive nationwide rights in a mark accrued to the first user nationally). The concept of geographic concurrent use contemplates that multiple parties have rights to use the same or confusingly similar marks in separate territories when such use in the same territory would otherwise constitute infringement. The test for infringement asks whether multiple parties using similar marks on goods or services in the same area would likely confuse reasonably prudent consumers as to the source, sponsorship, connection, or affiliation of the goods or services associated with the marks.¹ In determining each party's geographic territory of exclusive use rights, a

¹ The quintessential manner of confusion is confusion as to the source of the goods or services (i.e., confusion as to who supplies the goods or services). However, it is well established that infringement also contemplates consumer confusion as to a mark owner's sponsorship of, connection to, or affiliation with the infringing goods or services. See 15 U.S.C. §1114(1)(a) (2000) (describing an infringement as being, inter alia, any unauthorized use of a registered mark in relation to goods or services when such use "is likely to cause confusion, or to cause mistake, or to deceive") (emphasis added); 15 U.S.C. § 1125(a)(2000) (codifying these infringement concepts for Lanham Act § 43(a) actions); Comment, The Scope of Territorial Protection of Trademarks, 65 NW. U. L. REV. 781, 783–84 (1970)(discussing the broadening of the consumer confusion standard to include confusion resulting from consumers mistakenly inferring a mark owner's sponsorship of an infringing good or service); MCCARTHY, supra note 7, § 23:6 (discussing initial interest confusion, a species of confusion recognized by most courts wherein a consumer mistakenly affiliates a good or service with a mark's owner, even though the consumer actually knows the mark's owner does not make or sponsor the good or service); MCCARTHY, supra note 7, § 23:76 (maintaining that the foregoing likelihood of confusion concepts are applied by courts in determining infringement of registered marks under the Lanham Act).

court asks whether a likelihood of confusion exists in a particular area,² and if so, grants injunctive relief to the party with the superior rights—the senior user or good-faith remote junior user.³ In determining which party has superior rights, a tribunal initially makes the factual determination of the senior user’s geographic area of rights at the time the junior user adopted the mark.

Opposer’s oversimplified assumption that the Board would consider “the Web” to be a single market and presume a nationwide reputation from its activities (assuming some evidence of such was submitted by Opposer) via the Web should be avoided. With respect to the Internet, merely placing a mark on the Web does not accord a party a nationwide reputation. A reputation is rooted in consumer recognition, and the mere act of making a mark available nationally via the Web is a separate question from whether consumers have actually accessed the party’s mark or recognize it. Opposer’s memorandum and record before the Board is simply devoid of any evidence or proper analysis on these critical issues. As such, its motion should be denied.

Notwithstanding the dearth to absence of any analysis or evidence on these issues from Opposer, the determination of a party’s market, zone of goodwill, market penetration, and consumer association and recognition via the Internet or otherwise will necessarily be a fact-driven analysis; not one suited for or permitted on summary judgment.

IV. OPPOSER IS NOT ENTITLED TO SUMMARY JUDGMENT ON THE QUESTION OF LIKELIHOOD OF CONFUSION

Under In re E. I. du Pont de Nemours & Co., in testing for likelihood of confusion, the following, when of record, must be considered:

1. The similarity or dissimilarity of the marks in their entireties as to appearance, sound, connotation and commercial impression.

² See generally William Jay Gross, The Territorial Scope of Trademark Rights, 44 U. MIAMI L. REV. 1075, 1077 (1990); MCCARTHY, *supra* note 7, § 26:27 (“[Since] the territorial scope of trademark rights must be defined in terms of customer perception[, t]he touchstone of the determination of a trade area is likelihood of confusion.”).

³ Gross, *supra* note 64, at 1078; see also MCCARTHY, *supra* note 7, § 30:1 (“A prevailing plaintiff in a case of trademark infringement or false advertising is ordinarily entitled to injunctive relief of some kind.”) (quoting RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 35cmt. b (Tentative Draft No. 3, 1991)).

2. The similarity or dissimilarity of and nature of the goods or services as described in an application or registration or in connection with which a prior mark is in use.
3. The similarity or dissimilarity of established, likely-to-continue trade channels.
4. The conditions under which and buyers to whom sales are made, i.e. "impulse" vs. careful, sophisticated purchasing.
5. The fame of the prior mark (sales, advertising, length of use).
6. The number and nature of similar marks in use on similar goods.
7. The nature and extent of any actual confusion.
8. The length of time during and conditions under which there has been concurrent use without evidence of actual confusion.
9. The variety of goods on which a mark is or is not used (house mark, "family" mark, product mark).
10. The market interface between applicant and the owner of a prior mark:
 - a) a mere "consent" to register or use.
 - b) agreement provisions designed to preclude confusion, i.e. limitations on continued use of the marks by each party.
 - c) assignment of mark, application, registration and good will of the related business.
 - d) laches and estoppel attributable to owner of prior mark and indicative of lack of confusion.
11. The extent to which applicant has a right to exclude others from use of its mark on its goods.
12. The extent of potential confusion, i.e., whether *de minimis* or substantial.
13. Any other established fact probative of the effect of use.

In re E.I. du Pont de Nemours & Co., 476 F.2d 1357 (C.C.P.A. 1973). Contrary to Opposer's partial analysis of the In re E.I. du Pont de Nemours & Co. factors, there has been no articulation that the two factors mentioned by Opposer are more important than these others.⁴ In fact, the In re E.I. du Pont de Nemours & Co. case expressly states:

“[t]he evidentiary elements are not listed above in order of merit. Each may from case to case play a dominant role. In Schenley Distillers, Inc. v. General Cigar Co., Inc., 427 F.2d 783, 57 CCPA 1213 (1970), and in McKesson & Robbins, Inc. v. P. Lorillard Co., 120 USPQ 306 (TTAB 1959), element (9) led to a finding that confusion was unlikely when the same mark was used on a beverage and a tobacco product. In John Walker & Sons, Limited v. Tampa Cigar Company, Inc., 124 F. Supp. 254 (S.D. Fla. 1954), *aff'd*, 222 F.2d 460 (5th Cir. 1955) element (5) made confusion likely when the same mark was used on beverages and tobacco. See, also, Carling Brewing Company, Inc. v. Phillip Morris, Inc., 277 F. Supp. 326 (N.D. Ga. 1967) and Geo. A. Dickel Co. v. Stephano Brothers, 155 USPQ 744 (TTAB 1967) (involving beverages and tobacco).

⁴ Notably, the case Opposer cites in support of its errant proposition does not even state what Opposer claims it does. Indeed, the Board in Ava Enters. Inc. v. Audio Boss USA, Inc., 77 U.S.P.Q.2d 1783 (T.T.A.B. 2006) reiterated that “determination of the issue of likelihood of confusion is based on an analysis of *all* of the probative facts in evidence that are relevant to the factors set forth in In re E. I. duPont de Nemours & Co., 476 F.2d 1357, 177 USPQ 563 (CCPA 1973). See also, In re Majestic Distilling Company, Inc., 315 F.3d 1311, 65 USPQ2d 1201 (Fed. Cir. 2003)(emphasis added).

We find no warrant, in the statute or elsewhere, for discarding *any* evidence bearing on the question of likelihood of confusion. Reasonable men may differ as to the *weight* to give specific evidentiary elements in a particular case. In one case it will indicate that confusion is unlikely; in the next it will not. In neither case is it helpful or necessary to inject broad maxims or references to "the public interest" which do not aid in deciding. Only the facts can do that. In every case turning on likelihood of confusion, it is the duty of the examiner, the board and this court to find, upon consideration of *all* the evidence, whether or not confusion appears likely. That determination ends the decisional process.

In re E.I. du Pont de Nemours & Co., 476 F.2d at 1377.

In light of Opposer's utter failure to address each of the relevant factors, its motion for summary judgment must be denied.

Moreover, even if the limited matters raised by Opposer would have been a proper and sufficient In re E.I. du Pont de Nemours & Co. factors analysis (which Applicant does not concede), the so-called proffer of facts by Opposer would not have ended the inquiry because a proper analysis requires more than conclusorily (and incorrectly) stating the marks are identical and, therefore, there is likely to be consumer confusion. To the contrary, genuine issues of material fact remain regarding each matter raised.

A. The Marks Are Not Likely to Be Confused

An examination of the factors set forth in In re E.I. DuPont DeNemours & Co., 476 F.2d 1357 (CCPA 1973) reveals numerous unresolved issues of material fact, precluding summary judgment. Indeed, a cursory review of the record indicates that the factors overall support Applicant's contention that confusion is unlikely.

1. The marks are not identical.

Applicant filed its application to register MY HERO. Opposer has been using a myHERO logo on its anti-aging growth factor serum. It is plain to see the marks are not identical even in standardized form. Moreover, Opposer makes use of its myHERO logo only in the form shown in its own Exhibit A, i.e., "myHERO" (colored pin). The consumer public is not likely to mistake Applicant's standardized word mark for Opposer's variant design.

2. The marks create different commercial impressions.

The Applicant's mark and Opposer's mark create separate and distinct commercial impressions.

The mere fact that the marks (in standardized form only) contain similar terms does not justify a conclusion that the overall commercial impressions created by the marks as a whole are confusingly similar. See Conde Nast Publications, Inc., v. Miss Quality, Inc., 507 F.2d 1404, 1407 (CCPA 1975) (holding COUNTRY VOGUES not to be confusingly similar to VOGUE); In re Ferrero, 479 F.2d 1395, 1397 (CCPA 1973) (holding TIC TAC not to be confusingly similar to TIC TAC TOE); Plus Products v. General Mills, Inc., 188 U.S.P.Q. 520, 522 (TTAB 1975) (holding PROTEIN PLUS not to be confusingly similar to PLUS); In re Merchandising Motivation, Inc., 184 U.S.P.Q. 364, 367 (TTAB 1974) (holding MMI MENSWEAR not to be confusingly similar to MEN'S WEAR).

The test is not whether the marks can be distinguished when subjected to a side-by-side comparison, but rather whether the marks are sufficiently similar in terms of their overall commercial impressions that confusion as to the source of the goods or services offered under the respective marks is likely to result. H.D. Lee Co. v. Maidenform Inc., 87 USPQ2d 1715 (TTAB 2008) (holding that ONE FAB FIT is sufficiently visually and orally different from ONE TRUE FIT to create a different commercial impression; see also Shen Mfg. Co. v. Ritz Hotel, Ltd., 393 F.3d 1238, 73 USPQ2d 1350 (Fed Cir 2004) (RITZ and THE RITZ KIDS create different commercial impressions)).

Applicant's mark conveys the impression that its lotion will promote the general purposes of lotion in heroic fashion. Ward Decl., Exhibit 10 (Applicant Web Usage Images). In stark and differing contrast "the impression imposed on the consumer is that the anti-aging serum sold under Opposer's mark is the consumer's personal hero as its anti-aging effects are crafted and personalized for that particular consumer. The Opposer's mark conjures up images of a savior rescuing the consumer's face from the harsh reality of aging." **Ward Decl., Exhibit 9**

3. The nature of the goods identified by Applicant's mark is dissimilar to the goods identified by Opposer's marks.

The Applicant's goods identified by MY HERO are easily distinguishable from the goods identified by Opposer as they differ in nature, use and function. It is well established that the nature and scope of goods must be determined on the goods set forth in the application or registration. See

Hewlett-Packard Co. v. Packard Press Inc., 281 F.3d 1261, 62 USPQ2d 1001

(Fed. Cir. 2002); J&J Snack Foods Corp. v. McDonald's Corp. 932 F.2d 1460, 18 USPQ2d 1889(Fed. Cir. 1991).

Applicant's goods are identified in its application as cosmetics and Applicant's mark has been affixed to Applicant's lotion products. Ward Decl., **Exhibit 1 (Application)**. The Opposer's goods (as represented to the USPTO) are categorized as an anti-aging serum. Furthermore, Opposer's mark is used for goods that are applied to specific locations on a consumer's face to counter the effects of aging, specifically near the eyes and forehead. Applicant's goods do not "reverse" or counter the signs or effects of aging and Applicant's website does not tout it as such. In contrast, Opposer's advertising, packaging, marketing, and container prominently emphasize the anti-aging effects of its anti-aging serum. Accordingly, the goods identified by these marks have distinct uses and, therefore, are not sufficiently related to cause a likelihood of confusion.

4. The customers for the Applicant's goods and Opposer's anti-aging serum are different and would not expect the goods to emanate from the same source.

The goods identified by the Applicant's mark and Opposer's mark are not marketed to the same customers. When the goods of the parties are not marketed in a way that they would be encountered by the same consumers or give the incorrect assumption that they come from the same source, then, even if the marks are identical (which is not the case here), confusion is unlikely. See Quartz Radiation Corp. v. Comm/Scope Co., 1 USPQ 2d 1668 (TTAB 1986) (QR for coaxial cable held not confusingly similar to QR for various products (e.g., lamps, tubes) related to the photocopying field).

Opposer's goods are directed to reversing the signs of aging and, therefore, are marketed predominantly to women. Applicant's goods are directed to children as well as adults. A consumer looking to reverse the signs of aging would not be looking for body lotion to achieve the desired anti-aging result. And, a customer looking to moisten his body after a swim would not look at anti-aging serum.

Additionally, the goods in the Opposer's mark are solely "anti-aging serum" and goods in

Applicant's mark are cosmetics. Opposer's goods are not a laundry-list of goods but rather very specific goods intended for a very specific purpose – to reverse or reduce signs of aging. Customers searching for anti-aging serum would not likely believe that the Opposer's goods emanate from the same source as the goods represented by Applicant's mark. As Opposer previously argued to the USPTO, there would be no confusion because it target markets to a specific buyer, seeking a specific anti-aging product in the hopes of countering the effects of aging.

In this case, there is no likelihood of confusion. Because Opposer's specifically identified goods are not commercially or closely related to the goods represented by Applicant's mark, confusion as to the source of the goods is unlikely and summary judgment should be denied.

At best, all Opposer has done is raise the specter of a factual dispute regarding relatedness of the goods over non-identical marks. Specifically, even where marks are substantially identical (which Applicant denies), factual disputes over the relatedness of goods and services (which exist in this case) still preclude summary judgment. In Casper's Ice Cream v. Corn Products International, Inc., Opposition No. 91159086, 2006 WL 332549 (TTAB Feb. 8, 2006), applicant sought to register the mark CASCO for unmodified corn starch used as an ingredient in various food products and was opposed by that opposer's registration and longstanding use of CASCO for confections. The Board denied the motion for summary judgment, finding genuine issues of material fact regarding the overlap of purchasers, trade channels, marketing environments and strength of mark. See also L.C. Licensing, Inc. v. Cory Berma, Opposition No. 91162330, 2006 WL 983337 (TTAB Apr. 11, 2006) (ENYCE for automatic accessories versus ENYCE, ENYCE and design, and LADY ENYCE for men's, women's and children's apparel); Nanogen, Inc. v. Pharmwest, Inc., Opposition No. 91167477, 2006 WL 1355819 (TTAB May 15, 2006)(NANOGEN for cosmetics and nonmedicated skin and hair preparations versus NANOGEN for medical reagents and assays); and Centex Homes v. CitiHomes Realty Corp., Opposition No. 91161887, 2006 WL 1876344 (TTAB July 3, 2006) (CITIHOMEs for real estate brokerage services versus CITYHOMES residential home construction and real estate development).

5. The sophisticated consumer factor favors Applicant.

Opposer's anti-aging serum is expensive (\$225.00) for a one fluid ounce bottle. The product is advertised as a Growth Factor Anti-Aging Serum. It is beyond cavil to suggest that an ordinary consumer looking for body lotion and general cosmetics is going to be confused into buying a \$225.00 dollar anti-aging serum because of a close-looking name; especially when the name is identified in pink stylized letter-form versus standardized letters. Purchasers will not pay the costly serum price without first carefully considering its source and content. See Heartsprings, Inc. v. Heartspring, Inc., 143 F.3d 550 (10th Cir. 1998) (given the time and cost, parents and students of defendant's residential school are sophisticated purchasers). Those looking to "counter the effects of aging" through anti-aging serums and those looking for household body lotion are likely to know their respective personal needs and the respective industries for those products quite well. Thus, confusion will be highly unlikely.

B. Issues of Material Fact Exist Regarding Whether Opposer's Mark Should Be Classified in International Class 005 as a medicinal product versus International Class 003 as a generic skin cream.

During the course of these proceedings, it has come to the attention of Applicant that Opposer's anti-aging serum may and should be more properly classified as medicinal, requiring re-classification for purposes of this proceeding and Opposer's application pending before the USPTO. The matter is relevant because it impacts whether Applicant's products and Opposer's anti-aging serum are truly in the same classification and whether the commercial impressions are the same. Attached hereto are Warning Letters from the FDA which address product ingredients and claims of the effects of the anti-aging products of the particular manufactures which are similar to those of Opposer.

Under the Food, Drug, and Cosmetic Act (FD&C Act), a product intended to diagnose, mitigate, treat, or prevent disease, or to affect the structure or function of the body is classified as a drug (FD&C Act, Section 201(g)). If such a product is not generally recognized by qualified experts as safe and effective when used as labeled, it is a "new drug" (FD&C Act, Section 201(p)) and requires an approved New Drug Application to be marketed legally in the United States (FD&C Act, Section 505(a)). The

FDA has issued Warning Letters to manufacturers, citing drug claims associated with topical skin care, hair care, and eyelash/eyebrow preparations, noted on both product labeling and Web sites. Ward Decl., Exhibit 8 (Warning Letters).

On January 14, 2014, the FDA issued an import alert (Import Alert # 66-38) titled “Skin Care Products Labeled as Anti-Aging Creams.” The FDA stated its rationale being the numerous products on the market with:

“anti-aging” claims which cause the products to be unapproved new drugs. Examples of such claims are that the products “counteract,” “retard,” or “control” the aging process. Claims that the product will “rejuvenate,” “repair,” or “restructure” the skin may also be drug claims. A claim such as “molecules absorb and expand, exerting upward pressure to 'lift' wrinkles upward” is a claim for an inner structural change that would usually cause a product to be a drug.

Ward Decl., **Exhibit 11 (Import Alert)**

Furthermore, between April 17 and June 17, 1987:

Regulatory Letters were sent to several manufacturers of skin care products labeled with these types of claims. By letter of March 24, 1988, the Associate Commissioner for Regulatory Affairs informed these manufacturers that "Beginning 30 days after the date of this letter, any products found to be in substantial violation of the new drug and misbranding provisions of the act may be subject to regulatory action without prior notice.

Id.

Given this warning and the dearth of any legal analysis or evidence submitted by Opposer on the matter, fact questions remain regarding (1) whether Opposer or its product manufacturer received an FDA Warning Letter regarding its anti-aging serum; (2) whether Opposer’s anti-aging serum is or should be subject to FDA regulatory action; and (3) whether Opposer’s products should be more properly categorized and classified as drugs both by the FDA and the USPTO, respectively.


Accordingly, Opposer’s summary judgment motion should be denied.

V. CONCLUSION

For the foregoing reasons, Applicant requests that the Board deny Opposer’s Motion for summary judgment.

Dated: March 22, 2014

WARD LAW GROUP

By: 
Damon L. Ward
301 Fourth Avenue South
Suite 378N
Minneapolis, MN 55415
Telephone: (612) 353-9770
Fax: (866) 759-6030
E-mail: dward@wardlawgroup.com

Certificate of Service and Transmittal: I hereby certify that a copy of the foregoing **MEMORANDUM IN OPPOSITION TO OPPOSER'S MOTION FOR SUMMARY JUDGMENT** is being sent by first class mail, postage prepaid, to: MYBODY, LLC through its counsel Michael Hool, Hool Law Group, PLC, Suite 1020, 2398 East Camelback Road, Phoenix, AZ 85016 on the date specified below.

Dated: March 22, 2014


Damon L. Ward

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

In the matter of Application Serial No.: 85/597,114
Published in the Official Gazette on August 28, 2012

MYBODY, L.L.C.,

Opposer,

vs.

ERIC LUCAS,

Applicant.

Opposition No. 91206915

Declaration in Opposition to Opposer's
Motion for Summary Judgment

STATE OF MINNESOTA)
)
COUNTY OF HENNEPIN)

I, Damon L. Ward declare as follows:

1. That I am one of the attorneys retained by Applicant, and I am personally familiar with the pleadings during this litigation and submit this declaration in opposition to Opposer's Motion for Summary Judgment.
2. Attached hereto as Exhibit 1 is a true and correct copy of the application for Applicant's "MY HERO" trademark.
3. Attached hereto as Exhibit 2 is a true and correct copy of the Applicant's Notice of Publication.
4. Attached hereto as Exhibit 3 is a true and correct copy of the Office Action Refusal of Opposer's MYHERO mark for its anti-aging serum.
5. Attached hereto as Exhibit 4 is a true and correct copy the Notice of Taking Deposition of myBody, LLC.
6. Attached hereto as Exhibit 5 is a true and correct copy of myBody LLC advertising for its MYHERO log and packaging.
7. Attached hereto as Exhibit 6 is a true and correct copy of advertising showing the anti-aging serum ingredients.

8. Attached hereto as Exhibit 7 is a true and correct copy of an FDA Compliance and Regulatory information regarding the legal distinction and differences between drugs and cosmetics.
9. Attached hereto as Exhibit 8 is a true and correct copy of FDA Warning Letters.
10. Attached hereto as Exhibit 9 is a true and correct copy of the USPTO Refusal to register Opposer's MYHERO mark for its anti-aging serum.
11. Attached hereto as Exhibit 10 is a true and correct copy of Applicant's website images.
12. Attached hereto as Exhibit 11 is a true and correct copy of an e-mail from Opposer's counsel regarding discovery matters.
13. Attached hereto as Exhibit 7 is a true and correct copy of FDA Import Alert 66-38.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on: March 22, 2014



Damon L. Ward

Exhibits

Exhibit 1

PTO Form 1478 (Rev 9/2006)

OMB No. 0651-0009 (Exp 12/31/2014)

Trademark/Service Mark Application, Principal Register

TEAS Plus Application

Serial Number: 85597114

Filing Date: 04/13/2012

*NOTE: Data fields with the * are mandatory under TEAS Plus. The wording "(if applicable)" appears where the field is only mandatory under the facts of the particular application.*

The table below presents the data as entered.

Input Field	Entered
TEAS Plus	YES
MARK INFORMATION	
*MARK	MY HERO
*STANDARD CHARACTERS	YES
USPTO-GENERATED IMAGE	YES
LITERAL ELEMENT	MY HERO
*MARK STATEMENT	The mark consists of standard characters, without claim to any particular font, style, size, or color.
REGISTER	Principal
APPLICANT INFORMATION	
*OWNER OF MARK	Lucas, Eric
*STREET	2509 Mayflower Avenue
*CITY	Minnetonka
*STATE (Required for U.S. applicants)	Minnesota
*COUNTRY	United States
*ZIP/POSTAL CODE (Required for U.S. applicants only)	55305
PHONE	9525822928
EMAIL ADDRESS	eric@theoxygenplan.com

WEBSITE ADDRESS	www.theoxygenplan.com
LEGAL ENTITY INFORMATION	
*TYPE	INDIVIDUAL
* COUNTRY OF CITIZENSHIP	United States
GOODS AND/OR SERVICES AND BASIS INFORMATION	
* INTERNATIONAL CLASS	003
*IDENTIFICATION	Cosmetic preparations
*FILING BASIS	SECTION 1(b)
ADDITIONAL STATEMENTS INFORMATION	
*TRANSLATION (if applicable)	
*TRANSLITERATION (if applicable)	
*CLAIMED PRIOR REGISTRATION (if applicable)	
*CONSENT (NAME/LIKENESS) (if applicable)	
*CONCURRENT USE CLAIM (if applicable)	
ATTORNEY INFORMATION	
NAME	Damon L. Ward
FIRM NAME	Ward Law Group
INTERNAL ADDRESS	378N
STREET	301 Fourth Avenue South
CITY	Minneapolis
STATE	Minnesota
COUNTRY	United States
ZIP/POSTAL CODE	55415
PHONE	6123539770
FAX	18667596030
EMAIL ADDRESS	dward@wardlawgroup.com
AUTHORIZED TO COMMUNICATE VIA EMAIL	Yes
CORRESPONDENCE INFORMATION	

*NAME	Damon L. Ward
FIRM NAME	Ward Law Group
INTERNAL ADDRESS	378N
*STREET	301 Fourth Avenue South
*CITY	Minneapolis
*STATE (Required for U.S. applicants)	Minnesota
*COUNTRY	United States
*ZIP/POSTAL CODE	55415
PHONE	6123539770
FAX	18667596030
*EMAIL ADDRESS	dward@wardlawgroup.com
*AUTHORIZED TO COMMUNICATE VIA EMAIL	Yes
FEE INFORMATION	
NUMBER OF CLASSES	1
FEE PER CLASS	275
*TOTAL FEE PAID	275
SIGNATURE INFORMATION	
* SIGNATURE	/Damon L. Ward/
* SIGNATORY'S NAME	Damon L. Ward
* SIGNATORY'S POSITION	Attorney of Record, MN bar member
SIGNATORY'S PHONE NUMBER	6122823060
* DATE SIGNED	04/13/2012

Trademark/Service Mark Application, Principal Register

TEAS Plus Application

Serial Number: 85597114

Filing Date: 04/13/2012

To the Commissioner for Trademarks:

MARK: MY HERO (Standard Characters, see [mark](#))

The literal element of the mark consists of MY HERO.

The mark consists of standard characters, without claim to any particular font, style, size, or color.

The applicant, Eric Lucas, a citizen of United States, having an address of
2509 Mayflower Avenue
Minnetonka, Minnesota 55305
United States

requests registration of the trademark/service mark identified above in the United States Patent and Trademark Office on the Principal Register established by the Act of July 5, 1946 (15 U.S.C. Section 1051 et seq.), as amended, for the following:

For specific filing basis information for each item, you must view the display within the Input Table.

International Class 003: Cosmetic preparations

Intent to Use: The applicant has a bona fide intention to use or use through the applicant's related company or licensee the mark in commerce on or in connection with the identified goods and/or services. (15 U.S.C. Section 1051(b)).

For informational purposes only, applicant's website address is: www.theoxygenplan.com

The applicant's current Attorney Information:

Damon L. Ward of Ward Law Group
378N
301 Fourth Avenue South
Minneapolis, Minnesota 55415
United States

The applicant's current Correspondence Information:

Damon L. Ward
Ward Law Group
378N
301 Fourth Avenue South
Minneapolis, Minnesota 55415

6123539770(phone)

18667596030(fax)

dward@wardlawgroup.com (authorized)

A fee payment in the amount of \$275 has been submitted with the application, representing payment for 1 class(es).

Declaration

The undersigned, being hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. Section 1001, and that such willful false statements, and the like, may jeopardize the validity of the application or any resulting registration, declares that he/she is properly authorized to execute this application on behalf of the applicant; he/she believes the applicant to be the owner of the trademark/service mark sought to be registered, or, if the application is being filed under 15 U.S.C. Section 1051(b), he/she believes applicant to be entitled to use such mark in commerce; to the best of his/her knowledge and belief no other person, firm, corporation, or association has the right to use the mark in commerce, either in the identical form thereof or in such near resemblance thereto as to be likely, when used on or in connection with the goods/services of such other person, to cause confusion, or to cause mistake, or to deceive; and that all statements made of his/her own knowledge are true; and that all statements made on information and belief are believed to be true.

Signature: /Damon L. Ward/ Date Signed: 04/13/2012

Signatory's Name: Damon L. Ward

Signatory's Position: Attorney of Record, MN bar member

RAM Sale Number: 9395

RAM Accounting Date: 04/13/2012

Serial Number: 85597114

Internet Transmission Date: Fri Apr 13 12:16:06 EDT 2012

TEAS Stamp: USPTO/FTK-173.165.238.222-20120413121606

237898-85597114-49064d8c4405ef7804e5b963

f21f663e82-CC-9395-20120413120838096780

MY HERO

Exhibit 2



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Trademarks
P.O. Box 1451
Alexandria, VA 22313-1451
www.uspto.gov

Aug 8, 2012

NOTICE OF PUBLICATION

- | | |
|--------------------------------------|--|
| 1. Serial No.:
85-597,114 | 2. Mark:
MY HERO
(STANDARD CHARACTER MARK) |
| 3. International Class(es):
3 | |
| 4. Publication Date:
Aug 28, 2012 | 5. Applicant:
Lucas, Eric |

The mark of the application identified appears to be entitled to registration. The mark will, in accordance with Section 12(a) of the Trademark Act of 1946, as amended, be published in the *Official Gazette* on the date indicated above for the purpose of opposition by any person who believes he will be damaged by the registration of the mark. If no opposition is filed within the time specified by Section 13(a) of the Statute or by rules 2.101 or 2.102 of the Trademark Rules, the Commissioner of Patents and Trademarks may issue a notice of allowance pursuant to section 13(b) of the Statute.

Copies of the trademark portion of the *Official Gazette* containing the publication of the mark may be obtained from:

The Superintendent of Documents
U.S. Government Printing Office
PO Box 371954
Pittsburgh, PA 15250-7954
Phone: 202-512-1800

By direction of the Commissioner.

Email Address(es):

dward@wardlawgroup.com

Exhibit 3

To: MyBody, L.L.C. (uspto@hoollawgroup.com)

Subject: U.S. TRADEMARK APPLICATION NO. 85132776 - MYHERO - N/A

Sent: 6/13/11 11:05:57 AM

Sent As: ECOM105@USPTO.GOV

Attachments: [Attachment - 1](#)
[Attachment - 2](#)
[Attachment - 3](#)
[Attachment - 4](#)
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[Attachment - 40](#)

[Attachment - 41](#)

**UNITED STATES PATENT AND TRADEMARK OFFICE (USPTO)
OFFICE ACTION (OFFICIAL LETTER) ABOUT APPLICANT'S TRADEMARK APPLICATION**

APPLICATION SERIAL NO. 85132776

MARK: MYHERO

85132776

CORRESPONDENT ADDRESS:

MICHAEL D. HOOL
HOOL LAW GROUP, PLC
2398 E CAMELBACK RD STE 1020
PHOENIX, AZ 85016-9022

CLICK HERE TO RESPOND TO THIS LETTER:
http://www.uspto.gov/trademarks/teas/response_forms.jsp

APPLICANT: MyBody, L.L.C.

**CORRESPONDENT'S REFERENCE/DOCKET
NO:**

N/A

CORRESPONDENT E-MAIL ADDRESS:

uspto@hoolawgroup.com

OFFICE ACTION

STRICT DEADLINE TO RESPOND TO THIS LETTER

TO AVOID ABANDONMENT OF APPLICANT'S TRADEMARK APPLICATION, THE USPTO MUST RECEIVE APPLICANT'S COMPLETE RESPONSE TO THIS LETTER **WITHIN 6 MONTHS** OF THE ISSUE/MAILING DATE BELOW.

ISSUE/MAILING DATE: 6/13/2011

THIS IS A FINAL ACTION.

TEAS PLUS APPLICANTS MUST SUBMIT DOCUMENTS ELECTRONICALLY OR SUBMIT FEE: Applicants who filed their application online using the reduced-fee TEAS Plus application must continue to submit certain documents online using TEAS, including responses to Office actions. *See* 37 C.F.R. §2.23(a)(1). For a complete list of these documents, see TMEP §819.02(b). In addition, such applicants must accept correspondence from the Office via e-mail throughout the examination process and must maintain a valid e-mail address. 37 C.F.R. §2.23(a)(2); TMEP §§819, 819.02(a). TEAS Plus applicants who do not meet these requirements must submit an additional fee of \$50 per international class

of goods and/or services. 37 C.F.R. §2.6(a)(1)(iv); TMEP §819.04. In appropriate situations and where all issues can be resolved by amendment, responding by telephone to authorize an examiner's amendment will not incur this additional fee.

This Office action is in response to applicant's communication filed on June 10, 2011 in which applicant argued against the Trademark Act Section 2(d) refusal. The examining attorney has carefully considered the applicant's arguments but has found them unpersuasive. For the reasons set forth below, the refusal under Trademark Act Section 2(d) is now made FINAL with respect to U.S. Registration No. 1604253. See 15 U.S.C. §1052(d); 37 C.F.R. §2.64(a).

SECTION 2(d) REFUSAL – LIKELIHOOD OF CONFUSION

Registration of the applied-for mark was refused because of a likelihood of confusion with the mark in U.S. Registration No. **1604253**. Trademark Act Section 2(d), 15 U.S.C. §1052(d); see TMEP §§1207.01 *et seq.* See the previously enclosed registration.

Trademark Act Section 2(d) bars registration of an applied-for mark that so resembles a registered mark that it is likely that a potential consumer would be confused or mistaken or deceived as to the source of the goods of the applicant and registrant. See 15 U.S.C. §1052(d). The court in *In re E. I. du Pont de Nemours & Co.*, 476 F.2d 1357, 177 USPQ 563 (C.C.P.A. 1973) listed the principal factors to be considered when determining whether there is a likelihood of confusion under Section 2(d). See TMEP §1207.01. However, not all the factors are necessarily relevant or of equal weight, and any one factor may be dominant in a given case, depending upon the evidence of record. *Citigroup Inc. v. Capital City Bank Grp., Inc.*, ___ F.3d ___, 98 USPQ2d 1253, 1260 (Fed. Cir. 2011); *In re Majestic Distilling Co.*, 315 F.3d 1311, 1315, 65 USPQ2d 1201, 1204 (Fed. Cir. 2003); see *In re E. I. du Pont*, 476 F.2d at 1361-62, 177 USPQ at 567. In this case, the following factors are the most relevant: similarity of the marks, similarity of the goods, and similarity of trade channels of the goods. See *In re Dakin's Miniatures Inc.*, 59 USPQ2d 1593 (TTAB 1999); TMEP §§1207.01 *et seq.*

The overriding concern is not only to prevent buyer confusion as to the source of the goods, but to protect the registrant from adverse commercial impact due to use of a similar mark by a newcomer. See *In re Shell Oil Co.*, 992 F.2d 1204, 1208, 26 USPQ2d 1687, 1690 (Fed. Cir. 1993). Therefore, any doubt regarding a likelihood of confusion determination is resolved in favor of the registrant. TMEP §1207.01(d)(i).

Comparison of the Marks In General

In a likelihood of confusion determination, the marks are compared for similarities in their appearance, sound, meaning or connotation, and commercial impression. *In re E. I. du Pont de Nemours & Co.*, 476 F.2d 1357, 1361, 177 USPQ 563, 567 (C.C.P.A. 1973); TMEP §1207.01(b)-(b)(v). Similarity in any one of these elements may be sufficient to find the marks confusingly similar. *In re White Swan Ltd.*, 8 USPQ2d 1534, 1535 (TTAB 1988); see *In re 1st USA Realty Prof'ls, Inc.*, 84 USPQ2d 1581, 1586 (TTAB 2007); TMEP §1207.01(b).

Comparison of the Goods in General

The goods of the parties need not be identical or directly competitive to find a likelihood of confusion. See *Safety-Kleen Corp. v. Dresser Indus., Inc.*, 518 F.2d 1399, 1404, 186 USPQ 476, 480 (C.C.P.A. 1975); TMEP §1207.01(a)(i). Rather, it is sufficient to show that because of the conditions surrounding their marketing, or because they are otherwise related in some manner, the goods would be encountered by

the same consumers under circumstances such that offering the goods under confusingly similar marks would lead to the mistaken belief that they come from, or are in some way associated with, the same source. *In re Iolo Techs., LLC*, 95 USPQ2d 1498, 1499 (TTAB 2010); *see In re Martin's Famous Pastry Shoppe, Inc.*, 748 F.2d 1565, 1566-68, 223 USPQ 1289, 1290 (Fed. Cir. 1984); TMEP §1207.01(a)(i).

Analysis of the Marks

Applicant's mark, MYHERO shares the wording HERO which is the entirety of the registered mark HERO and therefore is confusingly similar to the registered mark in meaning or connotation and overall commercial impression.

Despite applicant's statement that the examining attorney has disregarded the "MY" component and "inappropriately changed the Applicant's mark," the fact is that the marks are compared in their entireties under a Trademark Act Section 2(d) analysis. *See* TMEP §1207.01(b). One feature of a mark may be recognized as more significant in creating a commercial impression; greater weight is given to that dominant feature in determining whether the marks are confusingly similar. *See In re Nat'l Data Corp.*, 753 F.2d 1056, 1058, 224 USPQ 749, 751 (Fed. Cir. 1985); *In re J.M. Originals Inc.*, 6 USPQ2d 1393, 1394 (TTAB 1987); TMEP §1207.01(b)(viii), (c)(ii).

In this case, the marks share the identical wording HERO which is the dominant portion of each of the marks. Marks may be confusingly similar in appearance where there are similar terms or phrases or similar parts of terms or phrases appearing in both applicant's and registrant's mark. *See Crocker Nat'l Bank v. Canadian Imperial Bank of Commerce*, 228 USPQ 689 (TTAB 1986), *aff'd sub nom. Canadian Imperial Bank of Commerce v. Wells Fargo Bank, Nat'l Ass'n*, 811 F.2d 1490, 1 USPQ2d 1813 (Fed. Cir. 1987) (COMMCASH and COMMUNICASH); TMEP §1207.01(b)(ii)-(iii).

Although applicant's mark includes the wording MY, please note that the mere addition of a term to a registered mark generally does not obviate the similarity between the marks nor does it overcome a likelihood of confusion under Trademark Act Section 2(d). *See In re Chatam Int'l Inc.*, 380 F.3d 1340, 71 USPQ2d 1944 (Fed. Cir. 2004) (GASPAR'S ALE and JOSE GASPAR GOLD); TMEP §1207.01(b)(iii). Here, the addition of the wording MY (which merely modifies the wording HERO) to the registered mark does not create a significantly different commercial impression from the registered mark.

Contrary to applicant's arguments, applicant's mark is not an unrecognizable term in which a consumer would not be able to discern the two terms MY and HERO. When viewing the mark MYHERO, a consumer would immediately recognize the terms MY and HERO being combined with the wording HERO being the most eye-catching term and the wording MY indicating possession. Applicant's argument that the mark "communicates the understanding that the goods, i.e. anti-aging serum, are uniquely tailored to the consumer's individual beauty needs" is unsupported and unpersuasive. *See* page 3 of applicant's response. A consumer would not parse out the wording MY and attribute it to goods but rather would assume that the MY is related to the HERO which is the word that immediately follows it. The mark is not "MYSERUMHERO" but "MYHERO". The differences in number of syllables and first two letters and pronunciation of the marks does not detract from the overall commercial impression of the marks as being MYHERO and HERO both featuring the identical wording HERO.

Ultimately, the question is not whether people will confuse the **marks**, but whether the marks will confuse people into believing that the goods they identify come from the same **source**. *In re West Point-Pepperell, Inc.*, 468 F.2d 200, 201, 175 USPQ 558, 558-59 (C.C.P.A. 1972); TMEP §1207.01(b). For that reason, the test of likelihood of confusion is not whether the marks can be distinguished when subjected to a side-

by-side comparison. The question is whether the marks create the same overall impression. *See Recot, Inc. v. M.C. Becton*, 214 F.3d 1322, 1329-30, 54 USPQ2d 1894, 1899 (Fed. Cir. 2000); *Visual Info. Inst., Inc. v. Vicon Indus. Inc.*, 209 USPQ 179, 189 (TTAB 1980). The focus is on the recollection of the average purchaser who normally retains a general rather than specific impression of trademarks. *Chemetron Corp. v. Morris Coupling & Clamp Co.*, 203 USPQ 537, 540-41 (TTAB 1979); *Sealed Air Corp. v. Scott Paper Co.*, 190 USPQ 106, 108 (TTAB 1975); TMEP §1207.01(b).

In this case, a consumer encountering the mark MYHERO in connection with applicant's goods will incorrectly believe that the goods originate from the same source as the registrant's HERO goods.

In addition, if the goods of the respective parties are "similar in kind and/or closely related," the degree of similarity between the marks required to support a finding of likelihood of confusion is not as great as would be required with diverse goods. *In re J.M. Originals Inc.*, 6 USPQ2d 1393, 1394 (TTAB 1987); *see Shen Mfg. Co. v. Ritz Hotel Ltd.*, 393 F.3d 1238, 1242, 73 USPQ2d 1350, 1354 (Fed. Cir. 2004); TMEP §1207.01(b).

Analysis of the Goods

Applicant's mark and the registered mark share the HERO component and therefore are confusingly similar. In addition, the applicant's goods are closely related to the registrant's goods. Applicant's goods are:

Non-medicated anti-aging serum

Registrant's goods are:

Men's cologne and after shave

To the extent that both of the parties provide beauty products, the goods are closely related. Neither the application nor the registration contain any limitations regarding trade channels for the goods and therefore it is assumed that registrant's and applicant's goods are offered everywhere that is normal for such items, i.e., beauty supply or cosmetics stores. Thus, it can also be assumed that the same classes of purchasers seek these goods and that consumers are accustomed to seeing them offered under the same or similar marks.

The trademark examining attorney previously attached evidence from the USPTO's X-Search database consisting of a number of third-party marks registered for use in connection with the same or similar goods as those of both applicant and registrant in this case. This evidence shows that the goods listed therein, namely **cologne, aftershave, and serum**, are of a kind that may emanate from a single source under a single mark. *See In re Davey Prods. Pty Ltd.*, 92 USPQ2d 1198, 1203 (TTAB 2009); *In re Albert Trostel & Sons Co.*, 29 USPQ2d 1783, 1785-86 (TTAB 1993); *In re Mucky Duck Mustard Co.*, 6 USPQ2d 1467, 1470 n.6 (TTAB 1988); TMEP §1207.01(d)(iii). Additional evidence is attached herein.

Applicant does not address the internet evidence that was attached to the prior Office Action proving that the goods of the parties are closely related if not identical. Nonetheless, attached is additional internet evidence demonstrating that the goods of the parties travel in the same channels of trade and are closely related or competitive, namely,

- Evidence from www.amazon.com offering "Swisa Dead Sea Mineral Skin Care Men's Moisturizing After Shave Balm and Skin Balancing Serum" which shows that after shave and serum are sold

together and by the same entity

- Evidence showing that the manufacturer “like organic skin care” offers both after shave as well as anti-aging serum
- Evidence from Beauty Orchid demonstrating that anti-aging serum products and cologne travel in the same channels of trade
- Evidence from Kiehl's offering entire categories of anti-aging products and shaving products
- Evidence from <http://www.neutrogena.com/> showing that anti-aging serum products and cologne and after shave originate from the same source under the same name.

The trademark examining attorney previously attached evidence from the USPTO's X-Search database consisting of a number of third-party marks registered for use in connection with the same or similar goods as those of both applicant and registrant in this case. This evidence shows that the goods listed therein, namely **cologne, aftershave, and serum**, are of a kind that may emanate from a single source under a single mark. See *In re Davey Prods. Pty Ltd.*, 92 USPQ2d 1198, 1203 (TTAB 2009); *In re Albert Trostel & Sons Co.*, 29 USPQ2d 1783, 1785-86 (TTAB 1993); *In re Mucky Duck Mustard Co.*, 6 USPQ2d 1467, 1470 n.6 (TTAB 1988); TMEP §1207.01(d)(iii). Additional evidence is attached herein.

Applicant argues that its goods are applied to specific locations on a consumer's face to counter the effects of aging whereas the registrant's goods are applied to various parts of the body to create a pleasurable fragrance and to reduce the burning and stinging associated with shaving. As previously explained, the goods of the parties need not be identical or directly competitive to find a likelihood of confusion. TMEP §1207.01(a)(i). As the evidence of record demonstrates, the goods are not only closely related in that they are beauty products, sold in the same channels of trade, and are often sold by the same source, but they are actually often the same thing (see the previously attached Elizabeth Grant's website demonstrating that after shave and serum are actually the same product). Where evidence shows that the goods at issue have complementary uses, and thus are often used together or otherwise purchased by the same purchasers for the same or related purposes, such goods have generally been found to be sufficiently related such that confusion would be likely if they are marketed under the same or similar marks. See *In re Martin's Famous Pastry Shoppe, Inc.*, 748 F.2d 1565, 1567, 223 USPQ 1289, 1290 (Fed. Cir. 1984) (finding bread and cheese to be related because they are often used in combination and noting that “[s]uch complementary use has long been recognized as a relevant consideration in determining a likelihood of confusion”); *Polo Fashions, Inc. v. La Loren, Inc.*, 224 USPQ 509, 511 (TTAB 1984) (**finding bath sponges and personal products, such as bath oil, soap, and body lotion, to be closely related because they are complementary goods that are likely to be purchased and used together by the same purchasers**).

Applicant's statement that its goods are targeted to women is not supported by any evidence or so narrowed in the identification of goods. There is no evidence that applicant is excluding men from its marketing campaign or would not invite men to purchase their goods. To the contrary, the evidence of record demonstrates that anti-aging serum is often targeted towards men just as much as it is towards women.

Summary of Analysis

A consumer encountering the mark MYHERO in connection with applicant's anti-aging serum will incorrectly believe that the goods originate from the same source as the registrant's HERO cologne and after shave. As a result, because of the confusingly similar marks and closely related and goods, registration is refused under Trademark Act Section 2(d) and made FINAL.

PROPER RESPONSE TO FINAL

If applicant does not respond within six months of the date of issuance of this final Office action, the application will be abandoned. 15 U.S.C. §1062(b); 37 C.F.R. §2.65(a). Applicant may respond to this final Office action by:

- (1) Submitting a response that fully satisfies all outstanding requirements, if feasible; and/or
- (2) Filing an appeal to the Trademark Trial and Appeal Board, with an appeal fee of \$100 per class.

37 C.F.R. §§2.6(a)(18), 2.64(a); TBMP ch. 1200; TMEP §714.04.

In certain rare circumstances, a petition to the Director may be filed pursuant to 37 C.F.R. §2.63(b)(2) to review a final Office action that is limited to procedural issues. 37 C.F.R. §2.64(a); TMEP §714.04; *see* 37 C.F.R. §2.146(b); TBMP §1201.05; TMEP §1704 (explaining petitionable matters). The petition fee is \$100. 37 C.F.R. §2.6(a)(15).

/Tasneem Hussain/
Trademark Examining Attorney
Law Office 105
(571) 272-8273
tasneem.hussain@uspto.gov

TO RESPOND TO THIS LETTER: Go to http://www.uspto.gov/trademarks/teas/response_forms.jsp. Please wait 48-72 hours from the issue/ mailing date before using TEAS, to allow for necessary system updates of the application. For *technical* assistance with online forms, e-mail TEAS@uspto.gov. For questions about the Office action itself, please contact the assigned trademark examining attorney. **E-mail communications will not be accepted as responses to Office actions; therefore, do not respond to this Office action by e-mail.**

All informal e-mail communications relevant to this application will be placed in the official application record.

WHO MUST SIGN THE RESPONSE: It must be personally signed by an individual applicant or someone with legal authority to bind an applicant (i.e., a corporate officer, a general partner, all joint applicants). If an applicant is represented by an attorney, the attorney must sign the response.

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mybody, My Hero, 1 fl. oz.

Part Number 181



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Price

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Availability: In Stock

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Description

Anti-Aging Growth Factor Serum

This heroic age-defying serum offers the best of the best ground-breaking anti-aging technologies in one single, multi-tasking product, including an exclusive growth factor complex proven to stimulate IGF-1 (Insulin Growth Factor 1), resulting in firmer and healthier looking skin.

- ideal for **AGING** skin type
- instantly helps to firm, tighten and brighten
- lessens the appearance of lines and wrinkles
- supports youthful collagen production
- minimizes the appearance of skin redness
- pH: 7.5



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myHERO™ Anti-Aging Growth Factor Serum

\$225

This heroic, age-defying serum works above and beyond the skin's surface to help repair damaged skin while restoring youthful luminosity and resilience. Proprietary ingredients tighten and brighten, resulting in firmer, healthier looking skin.

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Product Description

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- Lessens the appearance of lines and wrinkles
- Supports youthful collagen production
- Minimizes the appearance of skin redness

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\$115



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skin, in one bottle. myHERO includes an exclusive growth factor complex which stimulates IGF-1 (Insulin Growth Factor 1), providing your skin with a firmer and healthier look. This product is meant for aging and acne skin that needs to be firmed, tightened or brightened and can diminish the signs of fine lines and wrinkles while encouraging the production of collagen. Unlike many other products, myHERO provides results almost immediately for instant gratification of your efforts to make your skin flawless. Enjoy the long-term benefits of this unique bio emulsion while having skin that is silky smooth, beautiful and flawless once again. Ideal for AGING skin type, it instantly helps to firm, tighten and brighten, lessens the appearance of lines and wrinkles, supports youthful collagen production and minimizes the appearance of skin redness.

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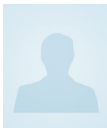
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Exhibit 5

PTO Form 1478 (Rev 9/2006)
OMB No. 0651-0009 (Exp 12/31/2011)

Trademark/Service Mark Application, Principal Register

TEAS Plus Application

Serial Number: 85132776

Filing Date: 09/18/2010

*NOTE: Data fields with the * are mandatory under TEAS Plus. The wording "(if applicable)" appears where the field is only mandatory under the facts of the particular application.*

The table below presents the data as entered.

Input Field	Entered
TEAS Plus	YES
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*MARK	MYHERO
*STANDARD CHARACTERS	YES
USPTO-GENERATED IMAGE	YES
LITERAL ELEMENT	MYHERO
*MARK STATEMENT	The mark consists of standard characters, without claim to any particular font, style, size, or color.
REGISTER	Principal
APPLICANT INFORMATION	
*OWNER OF MARK	MyBody, L.L.C.
*STREET	5080 North 40th Street, Suite 375
*CITY	Phoenix
*STATE (Required for U.S. applicants)	Arizona
*COUNTRY	United States
*ZIP/POSTAL CODE (Required for U.S. applicants only)	85018
PHONE	6028525500
FAX	6028525499

EMAIL ADDRESS	uspto@hoollawgroup.com
LEGAL ENTITY INFORMATION	
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* STATE/COUNTRY WHERE LEGALLY ORGANIZED	Arizona
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*INTERNATIONAL CLASS	003
IDENTIFICATION	Non-medicated anti-aging serum
*FILING BASIS	SECTION 1(b)
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*TRANSLITERATION (if applicable)	
*CLAIMED PRIOR REGISTRATION (if applicable)	
*CONSENT (NAME/LIKENESS) (if applicable)	
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ATTORNEY INFORMATION	
NAME	Michael D. Hool
FIRM NAME	Hool Law Group, PLC
STREET	2398 E. Camelback Road, Suite 1020
CITY	Phoenix
STATE	Arizona
COUNTRY	United States
ZIP/POSTAL CODE	85016
PHONE	6028525500
FAX	6028525499
EMAIL ADDRESS	uspto@hoollawgroup.com
AUTHORIZED TO COMMUNICATE VIA EMAIL	Yes
CORRESPONDENCE INFORMATION	
*NAME	Michael D. Hool

FIRM NAME	Hool Law Group, PLC
*STREET	2398 E. Camelback Road, Suite 1020
*CITY	Phoenix
*STATE (Required for U.S. applicants)	Arizona
*COUNTRY	United States
*ZIP/POSTAL CODE	85016
PHONE	6028525500
FAX	6028525499
*EMAIL ADDRESS	uspto@hoollawgroup.com
*AUTHORIZED TO COMMUNICATE VIA EMAIL	Yes
FEE INFORMATION	
NUMBER OF CLASSES	1
FEE PER CLASS	275
*TOTAL FEE PAID	275
SIGNATURE INFORMATION	
* SIGNATURE	/Therese Clark/
* SIGNATORY'S NAME	Therese Clark
* SIGNATORY'S POSITION	VP of Creative Development/Co-Founder
* DATE SIGNED	09/17/2010

Trademark/Service Mark Application, Principal Register

TEAS Plus Application

Serial Number: 85132776

Filing Date: 09/18/2010

To the Commissioner for Trademarks:

MARK: MYHERO (Standard Characters, see [mark](#))

The literal element of the mark consists of MYHERO.

The mark consists of standard characters, without claim to any particular font, style, size, or color.

The applicant, MyBody, L.L.C., a limited liability company legally organized under the laws of Arizona, having an address of

5080 North 40th Street, Suite 375

Phoenix, Arizona 85018

United States

requests registration of the trademark/service mark identified above in the United States Patent and Trademark Office on the Principal Register established by the Act of July 5, 1946 (15 U.S.C. Section 1051 et seq.), as amended, for the following:

For specific filing basis information for each item, you must view the display within the Input Table.

International Class 003: Non-medicated anti-aging serum

Intent to Use: The applicant has a bona fide intention to use or use through the applicant's related company or licensee the mark in commerce on or in connection with the identified goods and/or services. (15 U.S.C. Section 1051(b)).

The applicant's current Attorney Information:

Michael D. Hool of Hool Law Group, PLC

2398 E. Camelback Road, Suite 1020

Phoenix, Arizona 85016

United States

The applicant's current Correspondence Information:

Michael D. Hool

Hool Law Group, PLC

2398 E. Camelback Road, Suite 1020

Phoenix, Arizona 85016

6028525500(phone)

6028525499(fax)

uspto@hoollawgroup.com (authorized)

A fee payment in the amount of \$275 has been submitted with the application, representing payment for 1 class(es).

Declaration

The undersigned, being hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. Section 1001, and that such willful false statements, and the like, may jeopardize the validity of the application or any resulting registration, declares that he/she is properly authorized to execute this application on behalf of the applicant; he/she believes the applicant to be the owner of the trademark/service mark sought to be registered, or, if the application is being filed under 15 U.S.C. Section 1051(b), he/she believes applicant to be entitled to use such mark in commerce; to the best of his/her knowledge and belief no other person, firm, corporation, or association has the right to use the mark in commerce, either in the identical form thereof or in such near resemblance thereto as to be likely, when used on or in connection with the goods/services of such other person, to cause confusion, or to cause mistake, or to deceive; and that all statements made of his/her own knowledge are true; and that all statements made on information and belief are believed to be true.

Signature: /Therese Clark/ Date Signed: 09/17/2010

Signatory's Name: Therese Clark

Signatory's Position: VP of Creative Development/Co-Founder

RAM Sale Number: 6460

RAM Accounting Date: 09/20/2010

Serial Number: 85132776

Internet Transmission Date: Sat Sep 18 08:52:23 EDT 2010

TEAS Stamp: USPTO/FTK-24.248.83.57-20100918085223908

676-85132776-4709e32c3181589d6df55d554cd

e16ca54-DA-6460-20100914133306616795

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Exhibit 6

Exhibit 6

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mybody myHero Anti-Aging Growth Factor Serum

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Ships Within: 0-1 days

Product #: 1122674 UPC: 815965010083

ABOUT THE PRODUCT

Your new go-to product. The ground-breaking all-in-one myHERO Anti-Aging Growth Factor Serum offers almost immediate firming and tightening results.

This product firms, tightens, brightens, and diminishes fine lines and wrinkles while encouraging the production of new collagen.

ADDRESSES: AGING

1 fl oz

WHO IT'S FOR

Ideal for those with mature skin.

KEY INGREDIENTS

myGF3™ (Retinol, Glyceryl Diresinoate, Myristoyl Octapeptide-1, Myristoyl Octapeptide-2) - Proprietary complex; Focuses on cellular gene expression IGF-1 (Insulin Growth Factor 1) by improving the utilization of existing IGF levels to strengthen the dermis; Enhances the production of collagen without irritation to minimize the appearance of wrinkles and help prevent loss of elasticity.

Renovage™ (Treprenone) - Works on the origin of youth and targets the cell actors which guarantee lifespan and youth; clinically proven anti-aging effects: protects against stress by telomere stabilization and DNA maintenance (cell division)

Skin Tightener ST™ (Macrocystis Pyrifera Extract, Hydrolyzed Wheat Protein, PVP) - Proven plant and marine complex developed in France; the only aid of its type to create an instantaneous tightening and wrinkle reducing effect in around five minutes after application

HOW TO USE IT

Use AM/PM. Apply to face and neck.

CAUTION: For sensitive skin, use product every third night working up to nightly use. If irritation warrants, use the product less frequently or discontinue altogether.

Follow with Step 4: Protect & Serve Sun Shield (AM Only).

FULL INGREDIENTS

Water, Magnesium Ascorbyl Phosphate, Glycerin, Hydroxyethylcellulose, Retinol, Glyceryl Ditetinoate, Tocopheryl Acetate, Retinyl Palmitate, Myristoyl Octapeptide-1, Myristoyl Octapeptide-2, Myristoyl Nonapeptide-3, 1,2 Hexanediol, Tropolone, Dimethylmethoxy Chromanyl Palmitate, Pisum Sativum (Pea) Extract, Hydrolyzed Wheat Protein, Hydroxyphenyl Propamidobenzoic Acid, Bisabolol, Zingiber Officinale (Ginger) Root Extract, Macrocyctyl Pyrifera Extract, Safflower Glycides, Urea, Aloe Barbadensis Leaf Juice, Acetyl Carboxymethyl Cocoyl Glycine, Caprylic Glycol, Isoceteth-20, PEG-40 Stearate, Caprylic/Capric Triglyceride, Terepnone, Sucrose Dilaurate, Polysorbate 20, Trideceth-6, PVP, Sodium Polyacrylate, Dimethicone, Cyclopentasiloxane, PEG/PPG-18/18 Dimethicone, Pentylene Glycol, Tromethamine, Citric Acid, Lysolecithin, Polyglyceryl 10-Laurate, Safflower Acids, Cocoglycides, Butylene Glycol.

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**ABOUT OUR
MEDICAL DIRECTOR**

Mark B. Taylor, M.D. is a world-renowned dermatologist and cosmetic laser surgeon who has been in practice for over 30 years.

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Exhibit 7



U.S. Food and Drug Administration
Protecting and Promoting Your Health

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Cosmetics

Warning Letters Address Drug Claims Made for Products Marketed as Cosmetics

The Warning Letters appearing below illustrate an important legal distinction, the difference between a cosmetic and a drug under the [Federal Food, Drug, and Cosmetic Act](#)¹ (FD&C Act).

Under the FD&C Act, a product intended to diagnose, mitigate, treat, or prevent disease, or to affect the structure or function of the body is classified as a [drug](#)² (FD&C Act, Section 201(g)). If such a product is not generally recognized by qualified experts as safe and effective when used as labeled, it is a "new drug" (FD&C Act, Section 201(p)) and requires an approved New Drug Application to be marketed legally in the United States (FD&C Act, Section 505(a)). FDA issued Warning Letters to the following firms, citing drug claims associated with topical skin care, hair care, and eyelash/eyebrow preparations, noted on both product labeling and Web sites. Some examples of the drug claims cited are acne treatment, cellulite reduction, stretch mark reduction, wrinkle removal, dandruff treatment, hair restoration, and eyelash growth.

Warning Letter Addressing Eyelash and Eyebrow Treatments

- [Lifetech Resources, LLC](#),³ April 18, 2011

Warning Letters Addressing Topical Skin Care Preparations

- [USA Far Ocean Group Inc.](#),⁴ October 24, 2012
- [Skin Biology, Inc.](#),⁵ October 11, 2012
- [Avon Products, Inc.](#),⁶ October 5, 2012
- [Bioque Technologies](#),⁷ October 5, 2012
- [Andes Natural Skin Care LLC](#)⁸, September 21, 2012
- [Janson-Beckett, Inc.](#)⁹, September 21, 2012
- [Lancôme USA](#)¹⁰, September 7, 2012
- [Greek Island Labs](#)¹¹, September 7, 2012
- [Set-N-Me-Free Aloe Vera Co.](#)¹², June 12, 2012
- [JabaLabs, LLC](#)¹³, March 1, 2011
- [Fusion Brands International SRL](#)¹⁴, April 24, 2007
- [Freedom Plus Corporation](#)¹⁵, March 29, 2007
- [BioForm Medical, Inc.](#)¹⁶, February 15, 2007
- [Athletes.com, Inc./Higher Power, Inc., dba bodybuilding.com](#)¹⁷, July 7, 2006
- [Hydroderm Beverly Hills](#)¹⁸, September 26, 2005

- [Basic Research, LLC](#)¹⁹, January 20, 2005
- [University Medical Products USA, Inc.](#)²⁰, January 22, 2004

Warning Letters Addressing Hair Care Preparations

- [Skin Biology, Inc.](#),²¹ October 11, 2012
- [Greek Island Labs](#),²² September 7, 2012
- [Freedom Plus Corporation](#)²³, March 29, 2007
- [Global Vision Products, Inc.](#)²⁴, April 3, 2003
- [Pride and Power, Inc.](#)²⁵, March 3, 2003
- [Farouk Systems, Inc.](#)²⁶, July 24, 2002

For related information, see [Is It a Cosmetic, a Drug, or Both? \(or Is It Soap?\)](#)²⁷, ["Cosmeceutical"](#)²⁸ and [Warning Letters](#)²⁹.

Page Last Updated: 03/06/2014

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U.S. Department of **Health & Human Services**

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Exhibit 8
U.S. Food and Drug Administration
Protecting and Promoting Your Health

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Inspections, Compliance, Enforcement, and Criminal Investigations

Skin Biology, Inc. 10/11/12



Department of Health and Human Services

Public Health Service
Food and Drug Administration
Seattle District
Pacific Region
22215 26th Ave SE, Suite 210
Bothell, WA 98021

Telephone: 425-302-0340
FAX: 425-302-0402

October 11, 2012

OVERNIGHT DELIVERY SIGNATURE REQUIRED

In reply refer to Warning Letter SEA 13-01

Charlene Pickart, President/Co-Owner
Skin Biology, Inc.
4122 Factoria Boulevard SE, Suite 200
Bellevue, Washington 98006-5259

WARNING LETTER

Dear Ms. Pickart:

This is to advise you that the Food and Drug Administration (FDA) reviewed your website at the Internet address www.reverseskinaging.com in October, 2012. Based on this review, your "Copper Sun Tanning & Firming Body Lotion," "CP Serum," "BioHeal Cream," "LacSal Serum," "Exol Serum," "Folligen Spray," "TriReduction Cream," "Emu Oil S for Skin," "Protect & Restore Cream," and "Squalane" products appear to be intended for uses that cause these products to be drugs under section 201(g)(1)(B) and/or section 201(g)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B) and § 321(g)(1)(C)]. The claims on your website indicate that these products are intended for use in the cure, mitigation, treatment or prevention of disease and/or are intended to affect the structure or any function of the human body, rendering them drugs under the Act. The marketing of these products with claims evidencing these intended uses violates the Act.

Examples of some of the claims observed on your website include:

BioHeal Cream

In the "Benefits & Testimonials" tab on the purchase page for BioHeal and under the Testimonials tab on the main page of your website, your website contains claims in the form of the following personal testimonials:

- "I had two cysts on my face that would not heal . . . I finally ordered BioHeal and applied it. . . . The wounds turned darker and started to close up. Within a week, they were healed even though a crater type scar remained. . . . [M]y grandmother had a horrible case of shingles. Nothing the doctor gave her worked even after months of treatment. I brought down some BioHeal for her to use and 7 to 10 days later it was completely healed."
- "I had been burned by very hot coolant from my cars radiator after I opened the radiator cap. The physicians at the hospital thought I would need skin transplants but I started using BioHeal four days after the burn and had complete healing."

CP Serum and Emu Oil S for Skin

Under the "Eczema, Sjogrens" section in the "Skin Condition" category, in the "RESULTS" tab, your website contains the following claim:

- " 'It Worked for Me' . . . Problem: Eczema (a painful skin inflammation) on her index fingers and thumbs. What she did: tried a Copper-Peptide lotion (CP Serum) meant to be a skin care product, after reading a newspaper story about non-surgical ways to reduce wrinkles. . . . How she did it: Dawson's hands were so affected that 'there would be cracks and splits, and they'd be bleeding.' The story about Copper-Peptide creams mentioned that the creams were originally developed for burn victims and diabetics whose wounds wouldn't heal. . . . Small studies had shown that skin treated with Copper-Peptides had less pigmentation, reduced wrinkling . . ."

In the "Benefits & Testimonials" tab on the purchase page for Emu Oil S for Skin, your website contains claims in the form of the following personal testimonials:

- "[H]ad a patch of psoriasis on the side of one eye for years. Dermatologists gave me medicine for years without success. Four nights of the Emu Oil for Skin cleared the psoriasis."

Folligen Spray

In the "Benefits & Testimonials" tab on the purchase page for Folligen Spray, your website contains claims in the form of the following personal testimonials:

- "[A]fter just 3 applications of the Folligen Spray and Shampoo and Conditioner, I am thrilled to see my hair growing thicker and longer. The biggest bonus though is truly amazing - My hair is now returning to its original youthful brunette color . . ."
- "My 89 year old mother's hair was shedding and she had developed a bald spot. After she used Folligen Spray, the shedding stopped."

TriReduction Cream

Under the Testimonials tab on the main page of your website, your website contains a claim in the form of the following personal testimonial:

- "The TriReduction has done wonders . . . in reducing some flat warts elsewhere on my body . . ."

Copper Sun Tanning & Firming Body Lotion

In the "Benefits & Testimonials" tab on the purchase page for Copper Sun Tanning & Firming Body Lotion, your website contains a claim in the form of the following personal testimonial:

- "I live in Florida and have been using your copper peptides [an ingredient in this product] for three years. When I started my face had extensive sun damage. Recently, my face was examined with sun damage detection system (ultraviolet photography) and found to be free of sun damage except for a small area around my lips where I do not use the copper peptide creams."

Protect & Restore Cream

Under the Testimonials tab on the main page of your website, your website contains claims in the form of the following personal testimonials:

- "P&R cleared up the eczema on my hands in three days."
- "I have been trying your products with amazing results. I developed severe cystic acne once reaching the age of 35. I am having wonderful results with P & R #3. I would like to add, I have been to numerous dermatologists for years! There has never been one treatment that can compare to your product."

LacSal Serum and Exfol Serum

Under the "Acne" section in the "Skin Condition" category, in the "ABOUT THE CONDITION" tab, your website contains the following claim:

- "The key for reducing the appearance of pitted acne seems to be gently massaging LacSal Serum or Exfol Serum into the pitted scar on a daily basis to help slowly dissolve and remove scar tissue. . . . As scar tissue is replaced with healthy skin, the skin's surface seems to pull itself flat like a balloon."

Squalane

In the "Usage & How It's Different" tab on the purchase page for Squalane, your website contains the following claim:

- "Squalane/Squalene . . . compounds have some anti-cancer properties (Lee and Langer 1983) . . . In animal studies, mice were protected against the toxicity and injury of radiation when fed a diet supplemented with 2% Squalane (Storm et al, 1993). The compounds also have some anti-fungal properties and enhances the effects of Amphotericin B (Fungizone) against a variety of candida species Masuda et al, 1982)."

Under the Testimonials tab on the main page of your website, in the "Sensitive Skin Concerns Testimonials" section, your website contains the following claim:

- "I was amazed to see enough improvement on the first squalane application to apply makeup relatively smoothly, and within three days, I saw a 97% improvement in my dermatitis I highly recommend replacing at least one of the daily corticosteroid applications with squalane. It's more effective and carries none of the insidious medical risks of steroids."

Male Hair Loss

In the "ABOUT THE CONDITION" tab, you claim:

- "Many of our customers have reported that the combination of Folligen and emu oil often help revitalize hair. Recently, Dr. Michael Holick (Boston University Medical Center) reported a clinical study that found emu oil accelerated skin regeneration and also stimulated hair growth. He wrote - 'The hair follicles were more robust, the skin thickness was remarkably increased... Also, we discovered in the same test that over 80 percent of hair follicles that had been 'asleep' were awakened, and began growing hair.' "

Your products are not generally recognized as safe and effective for the above referenced uses; therefore, the products are "new drugs" as defined in section 201(p) of the Act [21 U.S.C. § 321(p)]. Under section 505 of the Act [21 U.S.C. § 355], new drugs may not be legally marketed in the United States without an approved New Drug Application (NDA). A description of the new drug approval process can be found on FDA's internet website at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm>¹. Any questions you may have regarding this process should be directed to the Food and Drug Administration, Division of Drug Information, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

Furthermore, your products "BioHeal Cream," "CP Serum," "Emu Oil S for Skin," and "Squalane" are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use these drugs safely for their intended purposes. Thus, these products are misbranded within the meaning of section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)] in that the labeling fails to bear adequate directions for use. The introduction of a misbranded drug into interstate commerce is a violation of section 301(a) of the Act [21 U.S.C. § 331(a)].

This letter is not an all-inclusive list of violations associated with your products or their labeling, and we have not attempted to list here all of the products that are promoted on your website for intended uses that cause them to be drugs. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. We advise you to review all of your websites, product labels, and other labeling and promotional materials for all your products to ensure that the claims you make for your products do not reflect intended uses that cause the distribution of the products to violate the Act.

We request that you take prompt action to correct all violations associated with your products, including the violations identified in this letter, and prevent their future recurrence. Failure to implement lasting corrective action of these violations may result in regulatory action being initiated by FDA without further notice. The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products [21 U.S.C. §§ 332 and 334].

Please notify this office in writing, within fifteen (15) working days from your receipt of this letter, of the current status of your corrective actions and the specific steps you have taken to correct the noted violations. Include any documentation necessary to show that correction has been achieved. If you do not believe that your products are in violation of the Act, include your reasoning and any supporting information for our consideration. If corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

Your written response should be sent to Lisa M. Althar, Compliance Officer, U.S. Food and Drug Administration, 22215 26th Ave SE, Bothell, Suite 210, Washington 98021. If you have any question about this letter, please contact Compliance Officer Lisa Althar at 425-302-0427.

Sincerely,
/S/

Charles M. Breen
District Director

cc: Loren Pickart, Vice-President/Co-Owner
Skin Biology, Inc.
4122 Factoria Boulevard SE, Suite 200
Bellevue, Washington 98006-5259

Page Last Updated: 10/22/2012

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Inspections, Compliance, Enforcement, and Criminal Investigations

Set-N-Me-Free Aloe Vera Co. 6/12/12



Department of Health and Human Services

Public Health Service
Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

June 12, 2012

CERTIFIED MAIL RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 12-24

Janet G. Heinrich, Owner and Managing Director
Set-N-Me-Free Aloe Vera Co.
19220 SE Stark Street
Portland, Oregon 97233-5751

WARNING LETTER

Dear Ms. Heinrich:

The Food and Drug Administration (FDA) reviewed your websites at the Internet addresses www.set-n-me-free.com and www.setnmefree.net in May 2012. Based on our review, we have determined that the products "Aloe Milk Moisturizing", "Aloe Moisture Cream", "Day-Night Emollients", "Moisturizing Aloe Lotion", "Aloe Comfrey Gel", "Aloe Facial Cleanser", "Aloe Stic", "99.5% Natural Aloe Liquid", "Lavender Spa Bath", "Aloe Heat Creme", "Aloe Body Wash" and "Set-N-Me-Free body wrap systems" are promoted for conditions that cause the products to be drugs under section 201(g)(1)(B) and/or 201(g)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 USC §§ 321(g)(1)(B) and 321(g)(1)(C)].

The therapeutic claims on your websites establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease and/or are intended to affect the structure or any function of the human body. The marketing of these products with these claims violates the Act. You may find the Act and the FDA's regulations through links on FDA's home page at www.fda.gov¹.

Examples of some of the product-specific claims observed on your website www.setnmeefree.net include:

Aloe Milk Moisturizing with Apricot / Aloe Milk Moisturizing

- "Apricot Kernel Oil [an ingredient in your product] supplies . . . a natural source of cancer fighting laeteryl lipids."
- "Borage Oil equals the GLA content found only in mother's milk. These unsaturated fats are incorporated into cell membranes to help with electron movement and insulate the body against heat loss. They prevent drying and flaking of skin; the precursors of hormone-like substances that supply collagen and elastin for better skin tone."

Aloe Moisture Cream

- "Natural B vitamins in the soy and safflower oils help in cell formation and build skin immune functions."
- "Soy protein [an ingredient in your product] is often documented as a cancer preventative agent."

Day-Night Emollients

- "Apricot kernel oil [an ingredient in the product] is high in gamma-linolenic acid that prevents the breakdown of elastic fibers and collagen that restores firmness to the tissues. These essential elements . . . are a natural source of cancer fighting laeteryl lipids."
- "Natural B-vitamins in the safflower and avocado oils [ingredients in this product] help in cell formation and build skin-immune functions. These oils renew skin flexibility by permeating natural vitamins A and E into skin cells, making regeneration of these cells occur faster."

Moisturizing Aloe Lotion

- "Natural B vitamins in the soy and safflower oils [ingredients in this product] help in cell formation and build skin immune functions. These oils renew skin flexibility by permeating vitamins A and E into skin cells, making regeneration of these cells occur faster. For these reasons soy oil is often suggested as a cancer preventative."

Aloe Comfrey Gel

- "First Aid in a Bottle"
 - "[S]tops acne eruptions and irritations"
 - "[A]ntiseptic for aftercare, helps with ingrown hair, acne eruptions."
 - "[T]reatment for psoriasis and eczema."
 - "[A]ids wounds and areas of infection."
- "[H]elp to prevent injuries to the skin tissues and increase the healing rate when these tissues are damaged."
- "Aloe vera [an ingredient in your product] is an antiseptic, fungicide and a bactericide. This natural wound serum speeds relief for burns, cuts, abrasions, and stops itch caused by tissue restoration or bug bites."
 - "[U]se Aloe Comfrey Gel generously . . . to heal the affected skin tissue area."

Aloe Facial Cleanser

- "The high B vitamin content of the soy oil [an ingredient in the product] restores the estrogen levels to the skin cells that help in blood cell formation and proper immune system functions for the skin. For these reasons, soy oil is often suggested as a cancer preventative."
 - "Chamomile [an ingredient in the product] is an anti-inflammatory and anti-microbial herb. This, along with the aloe, soothes irritation and reduces swelling or puffiness. This product is excellent for use on skin conditions such as eczema and psoriasis"

Aloe Stic

- "Aloe Stic contains 11% of this [tea tree oil] anti-inflammatory, anti-bacterial substance."
- "The lipophilic nature of tea tree oil enables it to chemically combine with fats and other lipids. The strong solvency of this oil assists in cleaning out and dissolving pustules and cysts. This obviously makes a great acne treatment."
- "Use this Aloe Stic to ease the dry, flaking and cracking skin on psoriasis areas. Comfort comes immediately to dry cracked feet by eliminating the inflammation of corns, calluses and bunions. Itching from insect bites, poison oak or rashes is stopped for hours after applying Aloe Stic."
 - "[S]lows recurring cold sores."

Natural Aloe Vera Liquid / 99.5% Natural Aloe Liquid

- "Spray or splash on rashes, sunburn, excema [sic], psoriasis patches for temporary itch and irritation relief."
- "Soak the feet in a pan of aloe liquid. The enzymes will soften calluses. Aloe's 'wound aiding' hormones will stop itching caused by athlete's foot fungus"

Aloe Lavender Spa Bath / Lavender Spa Bath

- "Lavender Spa Bath shows excellent results on psoriasis or eczema type skin problems."

Aloe Heat Creme

- "Use . . . as an arthritis relief."
- "[C]an easily become an arthritis treatment!"
- "Heat Creme works well with sprains, strains, torn ligaments, etc. It also relieves the discomfort of menstrual pain and headaches."

Aloe Body Wash

- "Aloe Body Wash shows excellent results on psoriasis or eczema type skin problems."
- "Set-N-Me-Free has documented that when obese people begin to use Aloe Body Wash daily, their body weight can drop several pounds during the first month."

Body Wrap Solution Gel

- "Aloe [an ingredient in the product] penetrates toxin-cleansing herbs through the protein wall of the fat cell. The herbs move stored toxins into the body's lymphatic system creating size loss."
- "Thus the herbs can move toxins from fat cells through intercellular osmosis, to the inner lymph system, creating a size loss."

In addition, your website www.set-n-me-free.com includes multiple claims about aloe vera gel generally that establish that these products, which contain aloe vera gel, are intended for use as drugs. For example:

Under the heading "Info" and under the subheading "Articles," on the page titled "PHARMACOLOGICAL ACTIVITIES OF ALOE VERA GEL":

- "It anesthetizes the tissue in the area to which it is applied relieving pain deep beneath the surface including pain associated with joints and sore muscles."
- "It is bactericidal when it is maintained in high concentration for several hours in direct contact with infectious bacteria."
 - "It is virucidal when in direct contact with high concentration for long periods of time."
 - "It is fungicidal under the same conditions."
 - "It is antipyretic-reduces the fever or heat of sores."

- "It is anti-inflammatory. Its action is similar to that of a steroid."
- "It is antipruritic-stops itching. (see Aloe Comfrey Gel)"
- "It breaks down and digests dead tissue including pus through action of proteolytic enzymes hastening the regenerative phase of healing."

Your products are not generally recognized as safe and effective for the above referenced uses and therefore, the products are "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

Furthermore, because these products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, adequate directions cannot be written so that a layman can use these products safely for their intended uses. Thus, these products are also misbranded within the meaning of section 502(f)(1) of the Act [21 U.S.C. § 352(f)(1)] in that the labeling for these products fails to bear adequate directions for use. The introduction of a misbranded drug into interstate commerce is a violation of § 301(a) of the Act, 21 U.S.C. § 331(a).

This letter is not an all-inclusive list of violations in your products and their labeling. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations. We advise you to review your websites, product labels, and other labeling and promotional materials for all your products to ensure that the claims you make for your product do not cause them to violate the Act.

You should take prompt action to correct the violations described above and prevent their future recurrence. Failure to implement lasting corrective action of these violations may result in regulatory action being initiated by FDA without further notice. The Act authorizes the seizure of illegal product; and injunctions against manufacturers and distributors of those products [21 U.S.C. §§ 332 and 334].

We request that you notify this office in writing, within fifteen working days from your receipt of this letter, of the specific steps you have taken to correct the noted violations. Include any documentation necessary to show that correction has been achieved. If corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

Please send your reply to the Food and Drug Administration, Attention: Cynthia White, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Cynthia White at (425) 302-0322.

Sincerely,
/S/
Charles M. Breen
District Director

Page Last Updated: 07/09/2012

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U.S. Department of **Health & Human Services**

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Inspections, Compliance, Enforcement, and Criminal Investigations

Lancome 9/7/12



Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

WARNING LETTER

SEP 7 2012

VIA CERTIFIED MAIL

Mr. Serge Jureidini
President
Lancôme USA
575 Fifth Avenue
New York, NY 10017

Re: 27359

Dear Mr. Jureidini:

This is to advise you that the Food and Drug Administration (FDA) reviewed your website at the Internet address <http://www.lancome-usa.com> in August 2012. Based on this review, your products Génifique Youth Activating Concentrate, Genefique Eye Youth Activating Eye Concentrate, Genefique Cream Serum Youth Activating Cream Serum, Génifique Repair Youth Activating Night Cream, Absolu Precious Cells Advanced Regenerating and Reconstructing Cream SPF 15 Sunscreen, Absolu Eye Precious Cells Advanced Regenerating and Reconstructing Eye Cream, Absolu Night Precious Cells Advanced Regenerating and Reconstructing Night Cream, and Rénergie Microlift Eye R.A.R.E.™ Intense Repositioning Eye Lifter appear to be promoted for uses that cause these products to be drugs under section 201(g)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(C)]. The claims on your web site indicate that these products are intended to affect the structure or any function of the human body, rendering them drugs under the Act. The marketing of these products with these claims evidencing these intended uses violates the Act.

Examples of some of the claims observed on your web site include:

Génifique Youth Activating Concentrate, Génifique Eye Youth Activating Eye Concentrate, and Génifique Cream Serum Youth Activating Cream Serum

- “[B]oosts the activity of genes and stimulates the production of youth proteins.”

Génifique Repair Youth Activating Night Cream

- “[B]oosts the activity of genes.”

Absolue Precious Cells Advanced Regenerating and Reconstructing Cream SPF 15 Sunscreen

- "A powerful combination of unique ingredients – Reconstruction Complex and Pro-Xylane™, a patented scientific innovation-- has been shown to improve the condition around the stem cells and stimulate cell regeneration to reconstruct skin to a denser quality."
- "See significant deep wrinkle reduction in UV damaged skin, clinically proven."

Absolue Eye Precious Cells Advanced Regenerating and Reconstructing Eye Cream and Absolue Nigh Precious Cells Advanced Regenerating and Reconstructing Night Cream

- "A powerful combination of unique ingredients – Reconstruction Complex and Pro-Xylane™, a patented scientific innovation-- has been shown to improve the condition around the stem cells and stimulate cell regeneration to reconstruct skin to a denser quality."

Rénergie Microlift Eye R.A.R.E.™ Intense Repositioning Eye Lifter

- "Immediate lifting, lasting repositioning. Inspired by eye-lifting surgical techniques . . . helps recreate a younger, lifted look in the delicate eye area."
- "[U]nique R.A.R.E. oligopeptide helps to re-bundle collagen."

Your products are not generally recognized among qualified experts as safe and effective for the above referenced uses and, therefore, the products are new drugs as defined in section 201(p) of the Act [21 U.S.C. § 321(p)]. Under section 505(a) of the Act (21 U.S.C. § 355(a)) a new drug may not be legally marketed in the U.S. without prior approval from FDA in the form of an approved New Drug Application (NDA). A description of the new drug approval process can be found on FDA's internet website at

[http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDeveloped¹andApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm²](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDeveloped1andApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm). Any questions you may have regarding this process should be directed to the Food and Drug Administration, Division of Drug Information, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Silver Spring Maryland 20993.

This letter is not an all-inclusive statement of violations associated with your products or their labeling, and we have not attempted to list here all of the products that are promoted on your website for intended uses that cause them to be drugs. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. We advise you to review your website, product labels, and other labeling for your products to ensure that the claims you make for your products do not reflect intended uses that cause the distribution of the products to violate the Act.

We request that you take prompt action to correct all violations associated with your products, including the violations identified in this letter. Failure to do so may result in enforcement action without further notice. The Act authorizes injunctions against manufacturers and distributors of illegal products and seizure of such products.

Please notify this office in writing within fifteen (15) working days of the receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify violations and make corrections to ensure that similar violations will not recur. If you do not believe that your products are in violation of the Act, include your reasoning and any supporting information for our consideration. If the corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which the corrections will be implemented.

Please direct your written reply to Rob Genzel, Jr., Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Compliance, Division of Enforcement(HFS-608), 5100 Paint Branch Parkway, College Park, Maryland 20740-3835.

Sincerely,
/S/
Michael W. Roosevelt
Acting Director
Office of Compliance
Center for Food Safety and Applied Nutrition

Close Out Letter

- [Lancome - Close Out Letter 11/19/12³](#)

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U.S. Department of **Health & Human Services**

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Inspections, Compliance, Enforcement, and Criminal Investigations

Janson-Beckett 9/21/12



Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

SEP 21 2012

WARNING LETTER

VIA CERTIFIED MAIL

Ian Strassler, President
Janson Beckett, Inc.
556 Route 73 South
West Berlin, NJ 08091

Re: 263155

Dear Mr. Strassler:

This is to advise you that the Food and Drug Administration (FDA) reviewed your web site at the Internet address <http://www.janson-beckett.com> in July 2012. Based on this review, your products DermaExcel 7; AlphaDerma CE; OkuSil Intensive Eye Rejuvenating Serum with 10% Argireline; 10% Argireline & Trace Mineral Enriched Facial Skin Prep; Vitamin C&C Facial Serum; Alpha Lipoic Acid Vitamin C Ester & DMAE Moisturizing Day Cream; Alpha Lipoic Acid Vitamin C Ester & DMAE Night Cream; and BeautiFull Lips™ Lip Plumper appear to be promoted for uses that cause these products to be drugs under section 201(g)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(C)]. The claims on your web site indicate that these products are intended to affect the structure or any function of the human body, rendering them drugs under the Act. The marketing of these products with claims evidencing these intended uses violates the Act.

Examples of some of the claims observed on your web site include:

DermaExcel 7

- "DermaExcel 7 is the first anti-wrinkle product to combine the three latest cutting edge peptides Each peptide interrupts the wrinkle producing [neurotransmitter process called the] SNARE complex differently but produces similar and collaborative results Reduced depth of wrinkles".
- "Leuphasyl helps moderate the release of acetylcholine ... by lowering the skin's electrical

charge in the applied area Leuphasyl's ability to moderate the electrical charge being sent to the applied area is crucial in lessening and relaxing muscle contraction. Impairing muscle contraction is what ... mitigates wrinkles and their formation."

- "Acetyl HexaPeptide (Argireline) ... was the first peptide to offer effects similar to BOTOX. Argireline works ... to block the nerve signals and by inhibiting the overproduction of catecholamines. By blocking these neurotransmitters, Argireline reduces the contraction of muscles and reduces wrinkles and prevents wrinkle formation."
- "HeptaPeptide (Snap-7) is a natural amino acid Snap-7' s advanced peptide structure is more efficient at stopping vesicle formation and neurotransmitter release than any other amino peptide. Snap-7 ... reduces deeper wrinkles Snap-7 accomplishes this by binding to existing Snap-25 receptors to block the release of acetylcholine. This prevents neurons from effectively transmitting signals that instruct muscles to contract. When repetitive movements are impaired, the formation of fine lines and wrinkles is reduced or prevented."
- "Because Leuphasyl lowers local synaptic voltage, neuron responsiveness and efficiency is lowered. Argireline and Snap-7 then work in concert to intercept any neurotransmitters actually released. This combined method of treatment prevents and lessens muscle contractions, subsequently reducing repetitive or expressive wrinkle formation."

AlphaDerma CE

- "Alpha Lipoic Acid, the most potent antioxidant on the market today, helps repair aged skin while preventing future damage."
- "VITAMIN C ESTER ... boosts protective antioxidant action and helps repair past damage by aiding new collagen production."
- "[U]sing AlphaDerma CE can extend the results of a Botox injection." (from FAQs page of web site)

OkuSil Intensive Eye Rejuvenating Serum with 10% Argireline

- "OkuSil's blend of ingredients helps to stimulate the circulation in the under eye area, thus reducing or eliminating these 'Dark Circles'. Once the proper circulation has been restored the dark circles will begin to fade along with the puffiness as they are directly related."

10% Argireline & Trace Mineral Enriched Facial Skin Prep (also referred to on your website as "Peptide Facial Skin Prep with Trace Minerals" and as "AH3 HexaPeptide Facial Skin Prep")

- "Sluggish cell energy, and thus, sluggish cellular response, can hinder peptide effectiveness. Using AH3 HexaPeptide Facial Skin Prep, under AlphaDerma CE and/or OkuSil. .. greatly improves skin response ... "

Vitamin C&C Facial Serum

- "Dual Source Vitamin C Promotes Collagen Synthesis"

- "[H]elps to protect against and repair environmental skin damage and signs of aging while stimulating collagen synthesis."

Alpha Lipoic Acid Vitamin C Ester & DMAE Moisturizing Day Cream and Alpha Lipoic Acid Vitamin C Ester & DMAE Night Cream

- "Alpha Lipoic Acid is a recognized powerful antioxidant that repairs existing skin damage, prevents future skin damage ... "
- "Vitamin C Ester (ascorbyl palmitate) ... increases our formula's protective antioxidant action while aiding in new collagen production."

BeautiFull Lips™ Lip Plumper

- "Methyl nicotinate, a vasodilator, is used in BeautiFull Lips to plump the lips by stimulating blood flow."
- "SepiLift® counteracts wrinkled, un-toned lips by stimulating collagen production, preventing enzyme destruction ... "

Your products are not generally recognized among qualified experts as safe and effective for the above referenced uses and, therefore, the products are new drugs as defined in section 201(p) of the Act [21 U.S.C. § 321(p)]. Under section 505(a) of the Act [21 U.S.C. § 355(a)] a new drug may not be legally marketed in the U.S. without prior approval from FDA in the form of an approved New Drug Application (NDA). A description of the new drug approval process can be found on FDA's internet website at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm>¹. Any questions you may have regarding this process should be directed to the Food and Drug Administration, Division of Drug Information, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

This letter is not an all-inclusive statement of violations associated with your products or their labeling, and we have not attempted to list here all of the products that are promoted on your website for intended uses that cause them to be drugs. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. We advise you to review your website, product labels, and other labeling for your products to ensure that the claims you make for your products do not reflect intended uses that cause the distribution of the products to violate the Act.

We request that you take prompt action to correct all violations associated with your products, including the violations identified in this letter. Failure to do so may result in enforcement action without further notice. The Act authorizes injunctions against manufacturers and distributors of illegal products and seizure of such products.

Please notify this office in writing within 15 working days of the receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify violations and make corrections to ensure that similar violations will not recur. If you do not believe that your products are in violation of the Act, include your reasoning and any supporting information for our consideration. If the corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be

implemented.

Please direct your written reply to Kathleen Lewis, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Compliance (HFS-608), Division of Enforcement, 5100 Paint Branch Parkway, College Park, Maryland 20740-3835.

Sincerely,

/S/

Michael W. Roosevelt
Acting Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

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U.S. Department of **Health & Human Services**

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Inspections, Compliance, Enforcement, and Criminal Investigations

Greek Island Labs 9/7/12



Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

WARNING LETTER

SEP 7 2012

VIA CERTIFIED MAIL

Radcliff Consultants, LLC
Agent for
Greek Island Labs
25 S. Arizona Place, Suite 520
Chandler, AZ 85225

Re: 26245

To Whom It May Concern:

This is to advise you that the Food and Drug Administration (FDA) reviewed your web sites at the Internet addresses <http://www.athenaskincare.com>, <http://adoniaorganics.com>, <http://www.greekislandlabs.com>, <http://www.lashalive.com>, <http://www.complexioncontrol.com>, <http://stemulift.com>, <http://www.7minutelift.com>, and <http://www.adonialegtone.com> in July 2012. Based on this review, your products Adonia LashAlive and BrowRevive Serum, Complexion Control Serum, Adonia StemuLift Serum, Athena 7 Minute Lift, Adonia LegTone Serum, and Athena Nightly Renewal Cream appear to be promoted for conditions that cause these products to be drugs under sections 201(g)(1)(B) and/or 201 (g)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B) and § 321(g)(1)(C)]. The claims on your web sites indicate that these products are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or articles intended to affect the structure or any function of the human body, rendering them drugs under the Act. The marketing of these products with claims evidencing these intended uses violates the Act.

Examples of some of the claims observed on your web sites include:

Adonia LashAlive and BrowRevive Serum

- **"Organic Cedarwood** ... helps to strengthen hair growth ... and combat ... hair loss."
- "Eucalyptus also offers antibacterial, anti-inflammatory benefits and can help to stimulate blood circulation on the scalp, encouraging hair growth..."
- **"Organic Lavender** ... Human clinical studies have reported that lavender essential oil may be beneficial in ... alopecia (hair loss) and as an antibacterial agent."

Complexion Control Serum

- "Blemish Free Skin in Just 3 Days!"
- "Clinically proven to reduce breakouts and blemishes by 84%"
- "Reduces white heads and black heads by 92%"
- "Organic Lime...has bactericidal...anti-inflammatory...properties."
- "[L]avender can...protect the skin while helping to prevent blemishes."
- "Palmarosa...helps in treating a range of skin infections..."
- "Organic Patchouli ...It also works aggressively to help prevent scarring."
- "Organic Petigraine...antiseptic properties help to clear...blemishes..."
- "Organic Thyme[,] a potent antimicrobial, antibacterial, and antifungal...recommended for many types of skin disorders."

Adonia StemuLift Serum

- "**Organic Geranium** ... effective cell regenerator ..."
- "**Organic Lavender** ... antiseptic ... properties ..."
- "**Organic Rosewood** ... cell stimulant and tissue regeneration properties ..."
- "**Organic Palmarosa** ... anti-infectious botanical, as well as an antifungal ... also helps in treating a range of skin infections while offering antiseptic ... benefits ..."
- "**Organic Rosemary Verbenone** ... Accelerates the cell's natural regenerative powers."
- "**Organic Everlasting** ... Cell-regenerative for skin, healing for scars (increases production of new cells)."
- "**Organic Thyme Linalool** ... Accelerates the cell's natural regenerative powers."
- "**Organic Neroli** ... prevent[s] scarring and stretch marks."
- "**Organic Patchouli** ... known as ... [an] antimicrobial ingredient ..."
- "**Organic Plant Stem Cells** ... reactivate your body's own dormant and weak skin stem cells, pushing them to regenerate."
- "**Organic Lemon Verbena** ... Acts as a[n] ... antiseptic and bactericide ... It also improves circulation and removes toxins, ensuring optimum circulation."
- "**Organic Cedarwood** ... used ... to ward off infections ..."

Athena 7 Minute Lift

- "[A] safe and effective alternative to Botox®."
- "[J]asmine oil is known for its anti-inflammatory properties"
- "Chamomile...celebrated for its...anti-inflammatory properties..."
- "[S]kin treatment with avocado oil significantly increases water soluble collagen."

Adonia LegTone Serum

- "**Organic Neroli Oil** ... used ... against plague and fevers."
- "Zingibain is an enzyme in ginger that has anti-inflammatory properties."

Athena Nightly Renewal Cream

- "Helps promote the development of collagen."
- "**Organic Chamomile** ...anti-inflammatory properties ..."

Your products are not generally recognized among qualified experts as safe and effective for the

above referenced uses and, therefore, the products are new drugs as defined in section 201(p) of the Act [21 U.S.C. § 321(p)]. Under section 505(a) of the Act (21 U.S.C. § 355(a)) a new drug may not be legally marketed in the U.S. without prior approval from FDA in the form of an approved New Drug Application (NDA). A description of the new drug approval process can be found on FDA's internet website at

[http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDeveloped¹andApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm²](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDeveloped1andApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm). Any questions you may have regarding this process should be directed to the Food and Drug Administration, Division of Drug Information, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Silver Spring Maryland 20993.

This letter is not an all-inclusive statement of violations associated with your products or their labeling, and we have not attempted to list here all of the products that are promoted on your website for intended uses that cause them to be drugs. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. We advise you to review your website, product labels, and other labeling for your products to ensure that the claims you make for your products do not reflect intended uses that cause the distribution of the products to violate the Act.

We request that you take prompt action to correct all violations associated with your products, including the violations identified in this letter. Failure to do so may result in enforcement action without further notice. The Act authorizes injunctions against manufacturers and distributors of illegal products and seizure of such products.

Please notify this office in writing within fifteen (15) working days of the receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify violations and make corrections to ensure that similar violations will not recur. If you do not believe that your products are in violation of the Act, include your reasoning and any supporting information for our consideration. If the corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be implemented.

Please direct your written reply to Latasha Robinson, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Compliance (HFS-608), Division of Enforcement, 5100 Paint Branch Parkway, College Park, Maryland 20740-3835.

Sincerely,
/S/
Michael W. Roosevelt
Acting Director
Office of Compliance
Center for Food Safety and Applied Nutrition

Page Last Updated: 09/10/2012

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Inspections, Compliance, Enforcement, and Criminal Investigations

Bioque Technology 10/5/12



Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

October 5, 2012

WARNING LETTER

VIA CERTIFIED MAIL

Christine Guilman
Bioque Technologies
200 Country Club Drive SW
Suite A-3
Blacksburg, VA 24060

Re: 262375

Dear Ms. Guilman:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.bioque.com> in August 2012. Based on this review, your products Serur XL, Serum Rejuvenate, C-Plus Moisturizing Cream, Rejuvenating Day Cream, Rejuvenating Night Cream, Pronto, **Formula 9 Firming Gel**, *Vitamin K1 8% Intensive Serum*, Gentle Purifying Skin Cleanser, and Liposome Cellulite Therapy appear to be promoted for uses that cause these products to be drugs under sections 201(g)(1)(B) and/or section 201(g)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FFDCA) [21 U.S.C. § 321(g)(1)(B) and § 321(g)(1)(C)]. The claims on your web site indicate that these products are drugs because they are articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or articles intended to affect the structure or any function of the body of man, rendering them drugs under the Act. The marketing of these products with claims evidencing these intended uses violates the Act.

Examples of some of the claims observed on your web site include:

Serum XL

- "Long-term repair - 5% each of two additional peptides with anti-oxidants stimulate production of collagen and elastin... helping to repair structural damage to deeper layers of the skin.
- "Argireline provides all the muscle-relaxing properties of BOTOX®..."
- "Argireline relaxes facial muscles beneath the deepest layer of skin to reduce tightening

around cavities caused by collagen and elastic deterioration, stopping the nasty process that furrows and puckers the outer layer of skin into - you guessed it -- wrinkles."

- "Serum XL packs in ...Vitamin E to heal scarring..."
- "[P]rovides the same benefits as Botox..."
- "Serum XL ... repairs the structural damage that actually causes those wrinkles"

Serum Rejuvenate

- **"Wrinkle reduction**—'Signal technology' in Intensive Penetrating Complex, a formula of active botanicals including penetrating liposomes and cell metabolism optimizers, activates production of collagen and elastane critical to rebuilding and maintaining healthy skin structure."
- "Intensive Penetrating Complex affects its long-term repair."
- "Damaged skin cells repair themselves and then replicate, creating healthier replacement cells."

C-Plus Moisturizing Cream

- **"Promotes collagen production**...repairing existing wrinkles..."
- "[C]ounters photo-aging, protecting and repairing skin from damage from UVA and UVB rays...improve skin's immune function and guard against free radical plaque that breaks down healthy skin structure"
- "Protection powerhouse C-Plus fends off UVA and UVB rays...and improves skin's immune system."

Rejuvenating Day Cream

- "Delivers a formula rich in peptides and active botanicals to fuel the rebuilding of skin structure and elasticity."
- "With regular use and in as little as four weeks, achieve a 42% increase in skin's firmness and a 37% reduction in fine lines and wrinkles."

Rejuvenating Night Cream

- "[F]ormula packed with peptides and active botanicals that fuel the rebuilding of skin structure"
- "With regular use and in as little as four weeks, achieve a 42% increase in skin's firmness and a 37% reduction in wrinkles and fine lines."
- "[H]igher concentration of beneficial elements promotes regeneration of skin cells during peak hours of sleep"

Pronto

- "[P]rovides BOTOX®-like results without needles..."
- "GABA travels down nerves and blocks the signals triggering facial muscles to contract, squint, frown, pucker, furrow, feather, and crease—stopping them in their tracks."
- **"Puts wrinkles on the rocks, without the BOTOX®"**

Formula 9 Firming Gel

- *"Power peptides penetrate with firming and tightening gels—quickly erases lines, tightens lids, sheds sags and banishes bags."*

Vitamin K1 8% Intensive Serum

- "Count on K1 to treat it all—varicose veins, age spots ... stretch marks, scars, bruises, rosacea and sun damage. Pat it on cleansed skin, and cure what ails ya!"

Gentle Purifying Skin Cleanser

- "Yucca extract frees skin of contaminants while clarifying skin, preventing acne..."
- "[I]t deposits...Vitamin C to build collagen, and Vitamin E to heal blemishes and scarring."

Liposome Body Sculpt Anti-Cellulite Therapy

- "This gel contains ingredients that, when absorbed into fatty deposit areas beneath the skin, is designed to stimulate blood flow and cell metabolism to help your body to naturally dissolve fat deposits."

Your products are not generally recognized among qualified experts as safe and effective for the above referenced uses and, therefore, the products are new drugs as defined in section 201(p) of the Act [21 U.S.C. § 321(p)]. Under section 505(a) of the Act [21 U.S.C. § 355(a)], a new drug may not be legally marketed in the U.S. without prior approval from FDA in the form of an approved New Drug Application (NDA). A description of the new drug approval process can be found on FDA's internet website at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm>¹. Any questions you may have regarding this process should be directed to the Food and Drug Administration, Division of Drug Information, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

This letter is not an all-inclusive statement of violations associated with your products or their labeling, and we have not attempted to list here all of the products that are promoted on your website for intended uses that cause them to be drugs. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. We advise you to review your website, product labels, and other labeling for your products to ensure that the claims you make for your products do not reflect intended uses that cause the distribution of the products to violate the Act.

We request that you take prompt action to correct all violations associated with your products, including the violations identified in this letter. Failure to do so may result in enforcement action without further notice. The Act authorizes injunctions against manufacturers and distributors of illegal products and seizure of such products.

Please notify this office in writing within 15 working days of the receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify violations and make corrections to ensure that similar violations will not recur. If you do not believe that your products are in violation of the Act, include your reasoning and any supporting information for our consideration. If the corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be implemented.

Please direct your written reply to Latasha Robinson, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Compliance (HFS-608), Division of Enforcement, 5100 Paint Branch Parkway, College Park, Maryland 20740-3835.

Sincerely,
/S/

Michael W. Roosevelt
Acting Director
Office of Compliance
Center for Food Safety and Applied Nutrition

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U.S. Department of **Health & Human Services**

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Inspections, Compliance, Enforcement, and Criminal Investigations

Avon Products, Inc. (U.S. Headquarters) 10/5/12



Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

October 5, 2012

WARNING LETTER

VIA CERTIFIED MAIL

Ms. Andrea Jung
Chairman and Chief Executive Officer
Avon Products, Inc.
Global Headquarters
1345 Avenue of the Americas
New York, NY 10105

Re: 262337

Dear Ms. Jung:

This is to advise you that the Food and Drug Administration (FDA) reviewed your web site at the Internet address <http://www.avon.com> in August 2012. Based on this review, your products Anew Clinical Advanced Wrinkle Corrector, Anew Reversalist Night Renewal Cream, Anew Reversalist Renewal Serum, Anew Clinical Therafirm Face Lifting Cream, and Solutions Liquid Bra Toning Gel appear to be intended for uses that cause these products to be drugs under section 201(g)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(C)]. The claims on your web site indicate that these products are intended to affect the structure or any function of the human body, rendering them drugs under the Act. The marketing of these products with claims evidencing these intended uses violates the Act.

Examples of some of the claims observed on your web site include:

Anew Clinical Advanced Wrinkle Corrector:

- "The at-home answer to wrinkle-filling injections. Start rebuilding collagen in just 48 hours."
- "4D WRINKLE-REVERSE TECHNOLOGY IS DESIGNED TO:
Rebuild collagen to help plump out lines and wrinkles.
Stimulate elastin to help improve elasticity and resilience.
Regenerate hydroproteins to help visibly minimize creasing."
- "Formulated to boost shock-absorbing proteins to help strengthen skin's support layers."

- "Improve fine & deep wrinkles up to 50%. Immediately plumps out wrinkles and fine lines. Within 48 hours begins boosting collagen production."

Anew Reversalist Night Renewal Cream & Anew Reversalist Renewal Serum

- "[W]rinkles are a result of micro-injuries to the skin, so AVON studied how skin heals. As part of the repair process, the body produces Activin . . . [E]xhaustive research, testing & review have resulted in an unprecedented discovery by AVON scientists: how to activate this key repair molecule. . . . Designed to boost Activin, ANEW's **Activinol** Technology helps reactivate skin's repair process to recreate fresh skin & help dramatically reverse visible wrinkles."

Anew Clinical Thermafirm Face Lifting Cream

- "Our effective lifting treatment is formulated to fortify damaged tissue with new collagen. In just 3 days, see tighter, firmer, more lifted skin."
- "[H]elp tighten the connections between skin's layers."

Solutions Liquid Bra Toning Gel

- "Formulated with pomegranate and fennel extracts to help boost production of collagen and elastin."

Your products are not generally recognized among qualified experts as safe and effective for the above referenced uses and, therefore, the products are new drugs as defined in section 201(p) of the Act [21 U.S.C. § 321(p)]. Under section 505(a) of the Act [21 U.S.C. § 355(a)], a new drug may not be legally marketed in the U.S. without prior approval from FDA in the form of an approved New Drug Application (NDA). A description of the new drug approval process can be found on FDA's internet website at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm>¹. Any questions you may have regarding this process should be directed to the Food and Drug Administration, Division of Drug Information, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

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We request that you take prompt action to correct all violations associated with your products, including the violations identified in this letter. Failure to do so may result in enforcement action without further notice. The Act authorizes injunctions against manufacturers and distributors of illegal products and seizure of such products.

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Please direct your written reply to Kathleen Lewis, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Compliance, Division of Enforcement (HFS-608), 5100 Paint Branch Parkway, College Park, Maryland 20740-3835.

Sincerely,

/S/
Michael W. Roosevelt
Acting Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

Page Last Updated: 10/13/2012

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Inspections, Compliance, Enforcement, and Criminal Investigations

Andes Natural 9/21/12



Department of Health and Human Services

Public Health Service
Food and Drug Administration
College Park, MD 20740

SEP 21 2012

WARNING LETTER

VIA CERTIFIED MAIL

Julio Bernabe, Managing Member
Andes Natural Skin Care LLC
1802 North Carson Street
Suite 108
Carson City, NV 89701

Re: 257974

Dear Mr. Bernabe:

This is to advise you that the U.S. Food and Drug Administration (FDA) reviewed your web sites at the Internet addresses <http://www.andes-natural.com>, <http://www.bioskincare.com>, <http://bioacnecare.com>, <http://bioskinforte.com>, <http://www.bioskinrepair.com>, and <http://bioskinexfol.com> in August 2012. Based on this review, your products BioSkinCare, Bio Skin Rejuvenation, BioSkinclear, Bio Acne Care, BioSkinforte, BioSkinexfol, and BioSkinrepair appear to be promoted for uses that cause these products to be drugs under sections 201(g)(1)(B) and/or 201(g)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(B) and § 321(g)(1)(C)]. The claims on your web sites indicate that these products are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or are intended to affect the structure or any function of the human body, rendering them drugs under the Act. The marketing of these products with claims evidencing these intended uses violates the Act.

Examples of some of the claims observed on your web sites include:

BioSkinCare (at www.andes-natural.com)

- "[T]riggers your body's own skin regeneration activators"

- "[R]epairs sun damaged tissues at the cellular level"
- "[T]akes away acne, rosacea, scars, skin blemishes and deep under skin lesions accumulated by excess UV exposure ... "
- "[T]akes away all imperfections and blemishes: acne, scars, keratosis bumps, razor nicks and burns, actinic keratosis lesions, ... eczema [sic], dermatitis, the effects on the skin of radiotherapy for cancer, blisters, scrapes, cuts ... "
- "[A]ctivates the fibroblast stem cells which favor the proliferation of new healthy connective tissues and all the structural elements of healthy skin, smoothing facial crater-like skin texture."
- "Inhibits microbiological activity of dangerous, pathogenic skin bacteria, including acne."
- "Regulates dermal fibroblast proliferation and excess collagen, and thus prevents and reduces abnormal scars such as keloid and hypertrophic scarring and slowly but consistently gets rid of ice-pick scars or pitted acne scars."
- "[Y]our skin will react to the biological enzymes by activating its own biological response modifiers thereby interacting with your body's immune system and repair mechanisms to treat skin injuries (cuts, bruises, abrasions, acne lesions, scarring), dysfunctional tissues (keratosis, keloid and hypertrophic scars ...) and prevent immune-mediated inflammatory skin disorders (inflammatory acne, rosacea, eczema and most dermatitis reactions)."
- "Topical application of the cream on skin wounds and scars regulates or decreases dermal fibroblast proliferation and excess collagen production, and thus prevents and reduces keloid and hypertrophic scarring."
- "[E]nhances the skin's natural regenerative responses by stimulating new capillary formation (angiogenesis), and the orchestrated biosynthesis of collagen, elastin and the water-holding proteoglycans and glycosaminoglycans."

Your web site also contains disease claims in the form of personal testimonials about your BioSkinCare product, including:

- "The scars in my upper arms ... are getting lighter."
- "I started to get severe acne on my face and neck ... I feel like I have found a miracle cure."
- "I have gotten not only my mother using it for her stretch marks ... but now my close friend for ... acne ... and ... it worked ... "
- "I ... have had cystic acne for 10 years ... I can't say that it completely prevents the cysts from appearing but they ... are much less frequent and much less severe."
- "I have ... used your product for an open wound (size of a pencil eraser) on a black mole removed by my doctor This product healed my wound faster than it would with an OTC prescription."

- "[T]he inflammation on my face has considerably reduced Also it has cleared up my psoriasis!"

Bio Skin Rejuvenation (at www.bioskinrejuvenation.com)

- "[R]educes melanin hyperpigmentation and a biomimetic peptide that inhibits the accumulation of melanin pigments."
- "[L]imiting both melanin production (tan) and skin reddening (erythema)."
- "Promotes cell proliferation and new synthesis of collagen and elastin "
- "Protects from UV A radiation"
- "Acts as an anti-inflammatory as it metabolizes or breaks down the denatured proteins into amino-acid components, which otherwise cause inflaming, and releases them for rebuilding of the skin structures"
- "Blocks melanin synthesis and reduces the formation of unwanted pigmentation, allowing control over skin tone and brown spots."
- "[T]he secretion has been used on patients that have been diagnosed with malignant tumors and need radio-therapy. The results have been highly satisfactory in radiodermatitis of neck and breasts."
- "The secretion also shows a UV A cytoprotective activity. It protects cells from noxious stimuli from Ultra Violet radiation which justifies the claim that applying it on skin protects the skin from UVA radiation."
- "[I]nhibiting the production of the enzyme tyrosinase, leading to clearer complexion and a reduction in skin pigmentation."
- "(R)egulates pigmentation tone for the total skin surface, lightening the complexion."
- "[E]liminating the INFLAMMATORY effect of a 'foreign body' induced by otherwise remaining denatured collagen"
- "[T]riggers the repair of cells damages by UV radiation "
- "[R]egulation of epidermal pigmentation tone."

BioSkinclear (at www.andes-natural.com/acne)

- "Gel for Acne & Rosacea Inflammation"
- "[E]liminates redness and post inflammatory hyperpigmentation."
- "Glycoconjugates also induce the proliferation on the surface of the skin of antimicrobial peptides that perform as natural antibiotics. And they signal your immune system that it is

being taken care of and moderates the inflammatory response so that it does not cause acne rashes or loss of tissues: ice-pick scars."

- "[R]elieves the side effects of Accutane®."
- "Topical application ... soon after the first signs of acne pimples, prevents the cells from initiating the signaling cascade that leads to acne inflammatory reactions and healing through the scarring pathway."
- "[N]ot only relieves the effects of acne breakouts & rosacea, it can also prevent acne breakouts and rosacea when used twice a day on clean skin as a routine skin care regimen to keep skin clear of blemishes."
- "It helps as well with the repair of everyday and accumulated damage created by exposure to UV radiation "
- "The gel has also been effective for the treatment of rosacea symptoms, helping to halt and prevent inflammation, restore the capacity of skin to intricately orchestrate its regeneration in an orderly way, strengthening blood vessels, cell walls and circulation; while helping to prevent further rosacea outbreaks."
- "Acne Scar Removal"
- "Heals micro-tears in the skin, softens coarse areas and opens constricting pores, plumps up ice-pick acne scars, shrinks raised or hypertrophic scars, reduces keloid scar tissues and stops their itching, and greatly diminishes post surgery scarring."
- "Protection from UV radiation "

Bio Acne Care (at www.bioacnecare.com)

- "Natural Solution for Zits, Pimples, Blemishes, Blackheads, Acne Breakouts."
- "[A] naturally occurring serum that supports the immune system of the skin by providing enzymes that dissolve blocked pores; skin regenerating activators that heal skin lesions; antimicrobials that keep bacteria under control ... cell communicating molecules that discern damaged cells from healthy cells and support the immune system in its fight against foreign matters and uncontrolled bacteria; and boosters of production of water holding molecules within the skin matrix that deeply moisturize the dermis & epidermis"
- "[L]icorice extract is anti-inflammatory, anti-irritant, anti-microbial ... & has a sebum regulation activity."

BioSkinforte (at www.bioskinforte.com)

- "Prevents and Clears Acne"
- "[P]owerful anti-inflammatory, antimicrobial and sebum regulation botanicals"

BioSkinexfol (at www.andes-natural.com/microdermabrasion and www.bioskinexfol.com)

- "[S]timulate collagen growth and cellular regeneration thereby improving ... sagging, reduction of imperfections and blemishes ... "
- "[R]emoval of ... abnormal scars and imperfections and the release of amino-acids that help rebuild damaged tissues quickly"
- "[D]issolve or 'digest' non functional, damaged and worn out cells deep within the skin. This explains why BIOSKINEXFOL works so well for old and rough stretch marks, for those are scar tissues deep within the skin."
- "[S]upports the protective strategies of the innate immune system of human skin ... "
- "The bioactive ingredients in BIOSKINEXFOL act as:
 - (1) regulators of enzyme activity;
 - (2) regulators of neurite outgrowth, and
 - (3) anti-inflammatory agents that limits oxidative damage after tissue injury;
 - (4) stabilizers, cofactors, and/or coreceptors for:
 - (4a) proteins produced by the human body that enable cells to communicate and effectively coordinate activities between one another (growth factors),
 - (4b) intracellular messenger molecules whose major function is to attract immune cells to sites of infection (chemokines), and
 - (4c) regulatory proteins released by cells of the immune system that act as intercellular mediators in the generation of an immune response (cytokines)."
- "The Glycoconjugates in the Cream help the skin to
 - (1) regenerate new collagen and elastin which improves skin firmness and elasticity,
 - (2) increase the production of water holding glycosaminoglycans which is true moisturizing,
 - (3) improve the skin's blood vessel microcirculation,
 - (4) increase the natural defense mechanism against oxidative damage, and
 - (5) repair damage to the protective skin barrier. As the skin is rebuilt and scars removed, the elastic properties of the skin pull it into a smooth surface. During skin remodeling, the old damaged protein is removed and replaced with new collagen and elastin fibers. This removes scar tissue, restores skin elasticity, and reduces wrinkles."

BioSkinRepair (at www.bioskinrepair.com)

- "[H]elps to prevent and reduce all types of scars, including hypertrophic and keloid scars, because it orchestrates an orderly repair of damaged skin, scarless healing & enhanced skin regeneration"
- "[S]timulating new capillary formation (angiogenesis), and the orchestrated biosynthesis and orderly deposition of new collagen, elastin, and the water-holding proteoglycans and glycosaminoglycans in the skin matrix "
- "Regulates dermal fibroblast proliferation and excess collagen, and thus helps to prevent and reduce scar keloids and hyperthropic scarring."
- "Stimulates the formation of the extracellular binding between cells "
- "[P]otent ... anti-inflammatory and anti-itching agent."
- "Inhibits microbiological activity of dangerous, pathogenic skin bacteria, including acne."
- "Stimulates the formation of glycosaminoglycans ... helps to thicken the dermis resulting in a lessening of sagging and less fine lines and wrinkles."

Your products are not generally recognized among qualified experts as safe and effective for the above referenced uses and, therefore, the products are new drugs as defined in section 201(p) of the Act [21 U.S.C. § 321 (p)]. Under section 505(a) of the Act [21 U.S.C. § 355(a)] a new drug may not be legally marketed in the U.S. without prior approval from FDA in the form of an approved New Drug Application (NDA). A description of the new drug approval process can be found on FDA's internet website at <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm>¹. Any questions you may have regarding this process should be directed to the Food and Drug Administration, Division of Drug Information, Center for Drug Evaluation and Research, 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

This letter is not an all-inclusive statement of violations associated with your products or their labeling, and we have not attempted to list here all of the products that are promoted on your website for intended uses that cause them to be drugs. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. We advise you to review your website, product labels, and other labeling for your products to ensure that the claims you make for your products do not reflect intended uses that cause the distribution of the products to violate the Act.

We request that you take prompt action to correct all violations associated with your products, including the violations identified in this letter. Failure to do so may result in enforcement action without further notice. The Act authorizes injunctions against manufacturers and distributors of illegal products and seizure of such products.

Please notify this office in writing within 15 working days of the receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify violations and make corrections to ensure that similar violations will not recur. If you do not believe that your products are in violation of the Act, include your reasoning and any supporting information for our consideration. If the corrective action cannot be completed within 15

working days, state the reason for the delay and the time frame within which the corrections will be implemented.

Please direct your written reply to Quyen Tien, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Compliance (HFS-608), Division of Enforcement, 5100 Paint Branch Parkway, College Park, Maryland 20740-3835.

Sincerely,

/S/

Michael W. Roosevelt
Acting Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

Page Last Updated: 09/26/2012

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U.S. Department of **Health & Human Services**

Links on this page:

1. <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/NewDrugApplicationNDA/default.htm>



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Inspections, Compliance, Enforcement, and Criminal Investigations

Jaba Labs 3/1/11



Department of Health and Human Services

Public Health Service
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

WARNING LETTER

MAR 1 2011

VIA OVERNIGHT DELIVERY

Joe Adams
JabaLabs, LLC
14080 Nacogdoches Road
#64
San Antonio, TX 78247

Re: 154172

Dear Mr. Adams:

This is to advise you that the Food and Drug Administration (FDA) reviewed your web sites at the Internet addresses <http://www.stemcellfacecream.com>¹ and <http://www.synovialabs.com>² in February 2011. Based on this review, FDA has determined that your products StemCellin Intensive Emulsion, StemCellin Deep Wrinkle Serum, and Faitoz-25 are promoted for uses that cause these products to be drugs under section 201(g)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)(C)]. The claims on your web sites establish that these products are drugs because they are intended to affect the structure or function of the human body. The marketing of these products with these claims violates the Act. You may find the Act and FDA regulations through links at FDA's home page at www.fda.gov³.

Examples of some of the claims found on your web site www.synovialabs.com⁴ include:

Claims for Faitoz-25 and its ingredients:

- "Lose your wrinkles! without painful injections"
- "The proven benefits of Faitoz-25
 - o Accelerates collagen and elastin production
 - o Restores firmness, [and] elasticity...
 - o Lose deep wrinkles in 30 days"
- "Reduce[s] expression lines & deep furrows"
- "The Argireline, Matrixyl 3000 and Snap-8 Peptides in Faitoz-25 wrinkle cream have [been] clinically shown to:
 - o Matrixyl 3000 decreases wrinkle volume
 - o Matrixyl 3000 decreases wrinkle density ...

- o Argireline increases skin firmness
- o Argireline increases skin thickness
- o Argireline increases collagen production"
- "Hyaluronic acid [an ingredient of Faitoz-25] helps reduce spider veins...."
- "Argireline mimics the actions of Botulinum by ... relaxing muscle contractions...."
- "Clinical trials have shown that Matrixyl 3000 is capable of reducing ... wrinkles that add years to your appearance. It was designed to promote collagen production while strengthening the essential structure of skin tissue."
- "Snap-8 [an ingredient of Faitoz-25] is known to ... reduce the depth of wrinkles ... in the forehead and around the eyes."
- "Vitamin C and E [ingredients of Faitoz-25] help ... protect skin cells from free radical damage."
- "Argireline locally disrupts nerve signals sent to muscles, relaxing the muscles"
- "SNAP-8 is a safer, cheaper, and milder alternative to Botulinum Toxin, topically targeting the same wrinkle-formation mechanism in the very same way."
- "Our greaseless Faitoz-25 serum formula ... improve[s] the elasticity of the skin, regenerate[s] skin stem cells, and effectively combat[s] wrinkles ... inflammation, and other symptoms of prematurely aging skin."

Your www.synovialabs.com⁵ web site also contains claims in the form of personal testimonials, including:

- "I have been using your wrinkle cream [Faitoz-25] for six weeks now. The skin around my eyes ... [has] less wrinkles."
- "Faitoz-25 wrinkle cream with 25% Argireline and Matrixyl 3000 does work in reducing my wrinkles.... I am always looking for products that make me look younger but until now I had not found any that work permanently."
- "Ever since I started using Faitoz-25 with 25% Argireline and Matrixyl 3000 three weeks ago I have noticed that the wrinkles on my forehead were less deep"

Examples of the claims found on your web site www.stemcellfacecream.com⁶ include:

Claims for StemCellin Intensive Emulsion and Deep Wrinkle Serum, and their ingredients:

- "StemCellin® with 5% PhytoCellTec™:
 - o Delays deterioration of essential skin cells
 - o Activates your own skin stem cells ...
 - o Reverses chronological aging"
- "This incredible PhytoCellTec apple stem cell cream emulsion is the first product to harness the regenerative potential of your own facial stem cells to renew skin It will actually 'rejuvenate' your skin by 'awakening' your body's own reservoir of undifferentiated stem-cells."
- "Our greaseless StemCellin PhytoCellTec stem cell cream formulas ... improve the elasticity of the skin, regenerate skin stem cells, and effectively combat wrinkles ... inflammation, and other symptoms of prematurely aging skin."
- "PhytoCellTec™ Malus Domestica is the first active [ingredient] based on plant stem cells to protect and repair skin stem cells.... The application of plant stem cell cultures to maintain and repair the function of skin stem cells is a breakthrough in anti-aging."
- "Rosehip seed oil [an ingredient of StemCellin] contains Vitamin A, which helps to delay the effects of skin aging ... and promotes collagen and elastin levels to increase. This results in firmer ... skin with greater elasticity."
- "Vitamin C [an ingredient of StemCellin] is a ... natural anti-inflammatory that helps in reversing some of the effects of sun damage."
- "Vitamin E [an ingredient of StemCellin] ... protect[s] skin cells from UV-induced damage It reduces inflammation ... by strengthening the skin's repair mechanisms."
- "PhytoCellTec™ Malus Domestica, the cosmetic ingredient in StemCellin stem cell cream, is based on an encapsulated extract of cultured apple stem cells that was tested in a clinical trial over 4 weeks with 20 subjects. This new stem cell cream ingredient was found to significantly

reduce wrinkles in the crow's feet area."

Your products are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. A new drug may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility to ensure that all of your products and labeling are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in enforcement action without further notice, such as seizure and/or injunction.

Please respond to this letter within fifteen working days from receipt with the actions you plan to take in response to this letter, including an explanation of each step being taken to correct the current violations and prevent similar violations. Include any documentation necessary to show that correction has been achieved. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

You should direct your written reply to Rob Genzel Jr., Compliance Officer, Food and Drug Administration, Center for Food Safety and Applied Nutrition, Division of Enforcement, Office of Compliance, 5100 Paint Branch Parkway (HFS-608), College Park, Maryland 20740.

Sincerely,

/s/

Michael W. Roosevelt
Acting Director
Office of Compliance
Center for Food Safety
and Applied Nutrition

Close out Letter

- [Jaba Labs Close out Letter 3/30/11](#)⁷

Page Last Updated: 04/07/2011

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U.S. Department of **Health & Human Services**

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2. <http://www.synovialabs.com>
3. <http://www.fda.gov>
4. <http://www.synovialabs.com>
5. <http://www.synovialabs.com>
6. <http://www.stemcellfacecream.com>
7. </ICECI/EnforcementActions/WarningLetters/ucm250292.htm>



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Inspections, Compliance, Enforcement, and Criminal Investigations

Hydroderm 25-Sep-05



Department of Health and Human Services

Public Health Service
Food and Drug
Administration

5100 Paint Branch Parkway
College Park, MD 20740

SEP 26 2005

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Randy Moss
President
Hydroderm Beverly Hills
8500 Higuera St.
Culver City, CA 90232
226 S . Beverly Drive
Beverly Hills, CA 90212
11240 Playa Ct.
Culver City, CA 90230

Dear Mr. Moss:

This letter is in reference to your firm's marketing and distribution of your Hydroderm brand product Body Shape Cellulite Toning Lotion, Fast-Acting Wrinkle Remover, Anti-Aging Eye Complex, and Intense Oil-Free Facial Moisturizer. The Food and Drug Administration (FDA) has reviewed your Internet web site at www.hydroderm.com (also accessible through www.hderm.com) and additional labeling for Body Shape Cellulite Toning Lotion, including the literature that accompanies this product when shipped to customers. This review shows serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) in the labeling of the above listed products. You can find the Act and implementing regulations through links on FDA's Internet website at www.fda.gov¹.

Under the Act, articles (other than food) intended to affect the structure or any function of the body of man are drugs [Section 201(g)(1)(C) of the Act, 21 USC 321(g)(1)(C)] . The labeling for your products includes claims that demonstrate that these products are intended to affect the structure or function of the body (structure/function claims). Examples of some of the structure/function claims observed in your products' labeling include :

- The product name implies structure/function effect. The combination of the terms "body shape" and "cellulite toning" imply that the product will affect the shape of the body by toning or reducing a type of subcutaneous fat (cellulite).

- Booklet entitled "body shape: cellulite reduction cream"

- o title of booklet

- o "This revolutionary cellulite reduction and slimming lotion will give you dramatic results"

- o "[T]he final step to your weight loss plan."

- o "Body Shape is clinically proven to . . .decreas[e] the fat layer on certain parts of the body. Body Shape's formula works by dehydrating the fat cells, reducing that 'cottage cheese' appearance"

- o "Body Shape is Clinically Proven to: . . .

- Reduce cellulite and diminish stretch marks

- o Increase metabolism in your body's fat cells"

- o "Body Shape uses a patented liposome delivery system, which transports the ingredients directly through the skin and into the fat cells. The active ingredients then dehydrate the fat cells, reducing the size of the individual fat cells and the thickness of the fat layer."

- o "Subjects were tested for 60 days and they lost up to 14% of the fat laywer in the stomach area and up to 2.1 inches per thigh!"

- o "Body Shape blocks an enzyme called phosphodiesterase, which is responsible for slowing down the fat breakdown process. When phosphodiesterase is being blocked, the fat breakdown process is sped up."

- o "Men and women have been looking for ways to reduce inches in their stomach, thighs, arms and hip area and Body Shape has helped people reach their objectives."

- o "This product can also been [sic] used on stretch marks and cellulite ."

- o "[S]ometimes it is virtually impossible to reduce fat in certain parts of your body. That is where Body Shape comes in."

- Pamphlet entitled "Body Shape: cellulite reduction cream"

- o "Whether you're trying to get rid of the stretch marks from a childhood growth spurt or are looking to slim down for summer, Body Shape can help you achieve your goals."

- o "Body Shape is the 'secret weapon' that will help tone and firm the areas that exercise alone can't shape."

- Additional claims that appear on your Internet web site www.hydroderm.com (claims already cited above are not included):

- o "Body Shape is perfect for men and women who are looking to reduce cellulite while firming and toning their body."

- o "Simply by massaging Body Shape into your skin twice a day, you can tone and firm those problem areas that diet and exercise can't shape on their own."

- o "Body Shape employs a liposome delivery system to transport its active ingredients These natural compounds help dehydrate fat cells, reducing their size and smoothing cellulite."

- o "Its scientific delivery system actually helps target cellulite and unsightly fat deposits on the body."

- o "Body Shape helps your body by:

- Reducing Cellulite . . .

- Dehydrating & Shrinking Fat Cells"

Your website also includes claims in the form of testimonials . Some examples are as follows :

- o "I am a certified personal trainer and have worked out for at least 15 years and have a very low fa

diet but it isn't enough to keep the cellulite off. BodyShape does the job."

o "I had lost a significant amount of weight over a two-year period and had, as one would expect, an excess of skin. Despite my continued efforts, I was unable to remedy this situation and was convinced that my only option left would be . . . plastic surgery. Hoping to avoid this, I tried BodyShape. I began using the product and was astonished with the results . . . [W]ithin eight weeks, the concerns were but a distant memory."

o "I have been using BodyShape for about three months (twice a day) and I absolutely love it! The cellulite on my thighs has been reduced by at least 50%. . . ."

o "[T]he cellulite on my inner and outer thigh is gone!"

Fast-Acting Wrinkle Reducer

- " The product name implies structure/function effect to reduce skin wrinkling.
- " Internet web site, www.hydroderm.com

o "This anti-aging skin serum helps reduce wrinkles and fine lines"

o "This fast acting wrinkle serum utilizes its patented Collagen Infusion Delivery System to deliver full collagen molecules to the skin, a feat previously available only by injection."

o "Hydroderm scientists developed the unique Collagen Infusion Delivery System, a transdermal formula that actually delivers whole collagen molecules directly to the skin"

o "Vyo-Serum helps support the new collagen. . . ."

o "[P]rovides the skin with, . . . whole collagen molecules that help restore and rejuvenate your skin's essential material."

o "Vyo-serum works as an instant lifting serum and active anti-aging ingredient."

o "[D]uring an independent clinical study, Hydroderm reduced wrinkled [sic] length and thickness by a combined 63.5%. . . ."

o "Life Extension magazine published an independent report on Hydroderm, attesting to its wrinkle-reducing effects."

o "[D]ermatologists have recommended Hydroderm as an alternative method of decreasing fine lines and wrinkles."

o (quoting article from Life Extension magazine) "Finally, . . . there was a topical liquid that produced many of the effects of injections without the pain and huge expense."

o (quoting article from Life Extension magazine) "Hydroderm has demonstrated efficacy in reversing the signs of certain aspects of skin aging. . . ."

o "Researchers noticed visible age-reversing effects, including a reduction in fine lines, diminished bags under the eye, and removal of irregular pigmentation ."

o "Hydroderm may reduce wrinkle length and width nearly by a combined 50%... ."

o "Hydroderm's patented Collagen Infusion Delivery System . . . delivers entire, intact collagen molecules and encourages quick and dynamic skin rejuvenation."

o (quoting article from Life Extension magazine) "[C]ollagen molecules are delivered directly to . . . the epidermis - an effect achieved previously only by injection ."

o "This formula produces a dramatic, visible improvement by providing whole collagen molecules that can restore and revive wrinkled, aged skin."

o "One woman who regularly used Botox® injections stated that Hydroderm® worked just as well."

Your website also includes claims in the form of testimonials. Some examples are as follows:

o "I was considering plastic surgery. But now I don't have to."

o "I do have all the tattletale signs of aging. And old products that don't work. But this truly does work. . . . It's the only anti-aging product I now use."

Anti-Aging Eye Complex

- The product name implies structure/function effect to protect against and counteract skin damage that results from skin aging.
- Internet web site, [ww-w.hydroderm.com](http://www.hydroderm.com)

o "Puffiness, Swelling, Dark Circles? Anti-Aging Eye Complex helps turn back the clock for the delicate skin around your eyes. This time-released serum helps reduce inflammation and encourages a constant flow of oxygenated blood to the eye area, to reduce dark circles and puffiness under the eyes."

o "Anti-Aging Eye Complex is a unique serum that diminishes the effects of aging in the delicate skin around your eyes."

o "MgCl [an ingredient in the product] acts as a vasodilator to open up blood vessels"

o "Tocopherol [an ingredient in the product]: protects skin from the damaging effects that result from exposure to UV rays, pollution, and harsh airborne elements."

o "Jojoba esters [an ingredient in the product]: reduces puffiness and dark circles."

o "Witch hazel [an ingredient in the product] : eases skin inflammation."

o "Anti-Aging Eye Complex is perfect for crow's feet as well as dark circles."

Intense Oil-Free Facial Moisturizer

Internet web site, www.hydroderm.com

o "Employing the universal botanical soother Aloe vera, this formula provides healing support to worn out skin. Legendary for its ability to help the body recover from injury, Aloe actually promotes restoration of the skin, fostering strong ties between your inner skin fibers."

These claims cause your products Body Shape Cellulite Toning Lotion, Fast-Acting Wrinkle Remover, Anti-Aging Eye Complex, and Intense Oil-Free Facial Moisturizer to be drugs as defined in section 201(g)(1)(C) of the Act [21 USC 321(g)(1)(C)] . Because your products are not generally recognized as safe and effective for the above referenced uses, the products are also new drugs as defined in section 201(p) of the Act [21 USC 321(p)]. Under section 505 of the Act (21 USC 355), a new drug may not be legally marketed in the U.S. without prior approval from FDA.

Your booklet entitled "body shape: cellulite reduction cream" includes structure/function claims for several of your other products (Fast-Acting Wrinkle Remover, Anti-Aging Eye Complex, and Intense Oil-Free Facial Moisturizer) similar to claims quoted from your website above. That booklet is additional evidence that those products are drugs because they are intended to affect the structure or function of the body.

This letter is not intended to be an all inclusive review of your products and their labeling. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

We request that you take prompt action to correct these violations . Failure to promptly correct these violations may result in enforcement action without further notice. The Act provides for the seizure of illegal products and injunctions against the manufacturer and/or distributor of illegal products.

In addition to the violations described above, we also note that the label of Body Shape Cellulite Toning Lotion declares its ingredients in two separate sections "Main Ingredients" and "Other Ingredients." This separate declaration is repeated on your Internet web site. The separate listing of "main" and "other" ingredients is inappropriate for a product marketed as a cosmetic. Cosmetic ingredients must be listed on the product label either in descending order of predominance (see 21 CFR 701 .3(a)) or grouped as specified in 21 CFR 701.3(f).

Please notify this office in writing within fifteen (15) working days of the receipt of this letter as to

the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify violations and make corrections to ensure that similar violations will not recur. If the corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be implemented.

Your reply should be sent to the attention of Compliance Officer Jennifer Thomas, US Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5 100 Paint Branch Parkway (HFS-607), College Park, Maryland 20740.

Sincerely,
/s/

John Kuerberg for Joseph R. Baca
Director
Office of Compliance
Center for Food Safety and Applied Nutrition

Page Last Updated: 07/08/2009

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Inspections, Compliance, Enforcement, and Criminal Investigations

Basic Research, LLC 20-Jan-05



Department of Health and Human Services

Public Health Service
Food and Drug Administration

Southwest Region
Denver District Office
Bldg. 20-Denver Federal
Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
FAX: 303-236-3100

January 20, 2005

AMENDED WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Dennis Gay
Chief Executive Officer
Basic Research, LLC
5742 W. Harold Gatty Drive
Salt Lake City, Utah 84116

Ref#: Den 05-06 Amended

Dear Mr. Gay:

We are amending our Warning Letter of January 14, 2005 to include your products Mamralin-ARa, and TestroGel and are re-issuing the letter with a January 20, 2005 date. Your expected date of response for all five products is now extended to fifteen working days after this date.

This letter is in reference to your firm's marketing and distribution of StriVectin-SD, StriVectin-SD Eye Cream, Dermalin-APg, Mamralin-ARa, and TestroGel. The Food and Drug Administration (FDA) has reviewed the labeling for these products, including your websites at www.kleinbecker.com and www.strivectin.com. FDA has determined that your products StriVectin-SD, StriVectin-SD Eye Cream, Dermalin-APg, Mamralin-ARa, and TestroGel are promoted with claims that cause the products to be drugs under section 201 (g)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 321(g)(1)(C)).

As defined in section 201 (g)(1)(C) of the Act, the term "drug" means articles (other than food) intended to affect the structure or function of the body. The labeling for your products includes several claims that demonstrate that these products are intended to affect the structure or function the body (structure/function claims). Examples of some of the structure/function claims observed in your products' labeling include:

StriVectin-SD:

- Intensive Concentrate For Existing Stretch Marks (Striae Distensae);
- Clinically Proven to Dramatically Reduce the Appearance of Existing Stretch Mark Length, Depth, Texture, and Discoloration;
- Optimum Glycosaminoglycan and Collagen Synthesis;
- Better than Botox®;
- A stretch-mark reducing emulsion . . . to diminish fine lines, wrinkles and crow's feet;
- Superior wrinkle-reducing properties of a patented oligo-peptide (called Pal-KTTKS)...on 'photo-aged skin';... [A] key ingredient in the StriVectin cream;
- Significant improvement; in wrinkle depth, length, wrinkle volume;
- Pal-KTTKS solution's effectiveness at reducing the appearance of fine lines and wrinkles...
- StriVectin-SD actually increases the synthesis of new collagen (StriVectin-SD increases collagen I synthesis by 117%, increases collagen IV synthesis by 357%, and increases glycosaminoglycan synthesis by 267%), making your skin; thicker and firmer;
- StriVectin-SD's clinically proven, proprietary compounds will produce a visible reduction in actual length, size, depth, feel, color, and rough texture of your existing wrinkles and/or stretch marks;
- Reduce wrinkles by as much as 68%, . . . and reduce the actual length depth, volume, and surface area of stretch marks/wrinkles;
- Q: Can StriVectin-SD® help with acne scars and other types of scarring?
A: Yes.... StriVectin-SD users have reported improvement in acne scars, burn scars, chicken pox marks, scars from old injuries, etc.;
- 93% of the subjects tested saw a dramatic difference in the depth, length, feel, color, and texture of stretch marks;
- Repair Existing Stretch Marks;
- Clinical observations further document the independent active StriVectin-SD isolates dramatically:
 - Decreased the actual length of striae (stretch marks)
 - Decreased the depth of indented surfaces
 - Increased smooth surfaces
 - Increased skin thickness
 - Increased skin firmness
 - Increased stimulation of collagen synthesis
 - Corrected irregularities in skin coloration;
 - StriVectin-SD: The Most Effective Stretch Mark Repair Compound Ever Developed;
 - Proven ability to significantly eradicate the scarred striations of stretch marks.. . .

StriVectin-SD Eye Cream (www.strivectin.com):

- Same active formula as the original StriVectin-SD®;
- StriVectin-SD (the stretch-mark-reducer-turned-anti-wrinkle-phenomenon
- Significant decrease in your existing wrinkles or stretch marks;

Dermalin-APg (www.kleinbecker.com):

- "The next-generation trapsepidermal fat emulsifying gel";

- Penetrating Gel Emulsifies Fat On Contact;
- Dissolves Deep-Stored Body Fat Wherever Applied.
- Reduces the accumulation of age-related body fat around your waist and abdomen.
- Actually reduce the size of saddlebag thighs.
- Penetrate the skin and shrink a woman's thigh.
- Releases fat stores from any problem area. When the fat is released from the back of a woman's thigh, the dimpled appearance disappears because tension on the connective tissue is reduced as stored depot fat is released. However, when the gel is applied to the tummy, waist or hips, a dramatic reduction of stored body fat occurs . . .
- Just apply.. . to your waist or tummy and watch them shrink in size within a matter of days.
- Wherever you've got those unsightly lumps and bumps, apply Dermalin-APg and they're gone.
- Forces the fat out of adipose tissue cells . . .
- One problem area at a time, until you've literally melted the fat and molded your body into a more pleasing shape.

Mamralin-ARa (www.Kleinbecker.com)

- Designed to protect a woman's breasts from sag and shrinkage caused by weight loss
- The Adenosine Receptor Agonists (ARAs) in Mamralin-ARa are designed to protect (and in many cases increase) the figure-enhancing fat stores in your bust.
- Inhibiting lipolysis (the process that causes the breast to release stored fat) and simulating fat uptake and retention.
- Makes it difficult for your body to deplete the fat stores in you breast for energy . . . maintaining (and in many cases increasing) the figure-enhancing fat stores in your bust . . .
- Helping you get rid of the excess, unwanted fat stored in your hips, thighs, abs, and buttocks . . .
- Applying Mamralin-ARa twice a day is the best way to avoid diet induced breast sag and shrinkage.

TestroGel (www.kleinbecker.com)

- TestroGel for Sexual Enhancement;
- Quickly raising androgen levels to give you (and your partner) the sexual confidence, stamina, and intensity it takes to truly satisfy.. -and be satisfied.
- Testosterone-Boosting Gel . . .
- Raise your testosterone levels without a doctor's prescription . . .
- Increase Testosterone Without Raising Estradiol Levels
- Suddenly become bigger, more ripped, more powerful, and more aggressive . . ."
- Have more muscle mass, more strength, and less body fat . . .
- A clinically verified alternative to prescription performance enhancers.

Furthermore, your products are not generally recognized as safe and effective for the above referenced uses and therefore, the products are considered new drugs under section 201(p) of the Act. New drugs may not be legally marketed in the U.S. without prior approval from FDA [section 505(a) of the Act].

This letter is not intended to be an all inclusive review of all claims, labeling, or products your firm

markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations. We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action without further notice. The Act provides for the seizure of illegal products, injunctions against the manufacturer and/or distributor of illegal products, and criminal sanctions against persons responsible for causing violations of the Act.

Please notify this office in writing within fifteen (15) working days of the receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to identify violations and make corrections to ensure that similar violations will not recur. If the corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be implemented.

Any reply should be sent to the attention of Compliance Officer Shelly L. Maifarth at the above address.

Sincerely,

/s/

B. Belinda Collins
District Director

Page Last Updated: 07/08/2009

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Inspections, Compliance, Enforcement, and Criminal Investigations

University Medical Products USA Inc. 22-Jan-04

Department of Health and Human Services' logo Department of Health and Human Services

Public Health Service
Food and Drug Administration
Los Angeles District
19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

VIA FEDERAL EXPRESS

January 22, 2004

W/L: 21-04

Raymond J. Francis
President & CEO
University Medical Products USA, Inc.
16912 Von Karman Avenue
Irvine, CA 92606

Dear Mr. Francis:

This letter is in reference to your firm's marketing and distribution of FACE LIFT Collagen 5 products, including Cell Regeneration Cream, Intensive Wrinkle Reducing Cream, and Intensive Lifting Complex; FACE LIFT Daytime Advanced Retinol-A, Nighttime Advanced Retinol-A, Advanced Under Eye Therapy, Vitamin C Anti-Wrinkle Patch, and Overnight Moisturizer; and BODY LIFT Anti-Cellulite Thigh Cream, Weight Reducing Cream, and Anti-Water Retention Lotion. Labeling for these products includes claims that establish their intended use to affect the structure or function of the body, which causes the products to be drugs, as defined in Section 201 (g)(1)(C) of the Federal Food, Drug and Cosmetic Act (the Act).

Objectionable claims that appear on the package labels for the three FACE LIFT Collagen 5 products listed above include the following:

- **Collagen5™ is proven to reduce deep wrinkles up to...70%.**
- Stimulates your skin's own collagen building network.
- Reduces deep wrinkles from within the skin's surface....
- Visible results that won't fade away....

Objectionable claims by product include:

Cell Regeneration Cream

- Helps boost collagen production
- Reduces deep wrinkles up to 70%
- Visibly Reduces Deep Wrinkles plus Fine Lines

Intensive Wrinkle Reducing Cream

- Helps boost collagen levels...
- Reduces deep wrinkles up to 70%

Intensive Lifting Complex

- Enhances collagen production

In addition, the product names "Cell Regeneration Cream" and "Intensive Wrinkle Reducing Cream" imply an effect on the structure or function of the body.

Objectionable claims that appear on the package labels for the BODY LIFT products include the following:

Anti-Cellulite Thigh Cream

- Significantly Reduces...Thigh Circumference
- Stimulate the beta receptors in cells to release stored fat.
- Clinically proven to...reduce thigh circumference.

Weight Reducing Cream

- Fat Burning Formula
- Controls appetite and Increases Metabolism
- Lose Inches & Pounds
- Helps control your appetite and break down unwanted fat.. . .
- Help shed unwanted fat....
- Stimulates your body's natural ability to break down fat cells, helping to suppress the appetite, accelerate metabolism and burn fat.

Anti-Water Retention Lotion

- Eliminates Bloating & Water Retention
- Helps reduce water retention in the stomach, hips and legs....

In addition, the product names "Weight Reducing Cream" and "Anti-Water Retention Lotion" imply an effect on the structure or function of the body.

Your Internet web site, www.universitymedical.com, also includes claims about the FACE LIFT Collagen 5 products and other products you market that similarly establish the intended use of these products as drugs. Objectionable claims on your website include the following:

FACE LIFT Collagen 5 Products (listed on website as "Collagen 5 for Deep Wrinkles")

- The only advanced collagen replenishment line....
- Replenishes your skin's own, natural collagen.
- Reduced deep wrinkles up to 70% in clinical studies.

Daytime Advanced Retinol-A™ and Nighttime Advanced Retinol-A™

- Help stimulate collagen and elastin renewal.

Advanced Under Eye Therapy™

- Effective active ingredients Vitamin C and Retinol-A help visibly firm and smooth away fine line:

and wrinkles.

- Green Tea extract helps reduce puffiness, while...healing ingredients help to fade dark circles

Vitamin C Anti-Wrinkle Patch™

- Vitamin C helps reduce the effects of aging...by helping to strengthen collagen and elastin fibers.
- Clinical studies proved a 50% reduction in wrinkles....

Overnight Moisturizer™

- Helps to calm, relax and promote restful sleep.
- Helps skin cells renew and repair themselves....

Because these drugs are not generally recognized as safe and effective when used as labeled, they are new drugs under section 201(p) of the Act. A new drug may not be legally marketed in this country without an approved New Drug Application (NDA) [Section 505(a) of the Act].

This letter is not intended to be an all inclusive review of the labeling for all products your firm may market. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of the receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to assure that similar violations will not recur. If the corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be implemented.

Your reply should be sent to the Food and Drug Administration, Los Angeles District Office, 19701 Fairchild Street, Irvine, CA 92612. If you have any questions relating to this letter, please contact Barbara Rincon, Compliance Officer at (949) 608-4439.

Sincerely,

/S/

Alonza E. Cruse
Director, Los Angeles District

Page Last Updated: 07/08/2009

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U.S. Department of **Health & Human Services**

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Exhibit 9

UNITED STATES PATENT AND TRADEMARK OFFICE
TRADEMARK EXAMINING OPERATIONS
RESPONSE TO OFFICE ACTION

Applicant:	MYBODY, L.L.C.)	Trademark Law Office: 105
Mark:	MYHERO)	
Serial No.:	85132776)	Examining Attorney:
Filed:	September 18, 2010)	Tasneem Hussain
)	
)	Mailing Date of Action:
)	December 27, 2010
)	

I. Introduction

In an Office Action dated December 27, 2010 (the “Refusal”), the Examining Attorney refused registration of Applicant’s mark MYHERO. The Examining Attorney concluded that a likelihood of confusion exists between Applicant’s use of MYHERO for “non-medicated anti-aging serum” and the registered mark HERO, U.S. Registration No. 1,604,253, for “men’s cologne and after shave” (the “Cited Mark”).

This response to the Refusal demonstrates that Applicant’s use of MYHERO is not likely to be confused with the Cited Mark.

II. Remarks

A. No Likelihood of Confusion Exists Between Applicant’s Use of MYHERO and the Cited Mark.

The Examining Attorney’s conclusion that likelihood of confusion exists between Applicant’s use of MYHERO and the Cited Mark rests on three bases: (1) similarity of the marks; (2) similarity of the goods and/or services; and (3) similarity of the trade channels of the goods and/or services.

This response establishes that (i) Applicant’s mark and the Cited Mark differ when the marks are viewed in their entirety; (ii) Applicant’s mark creates a very different commercial impression from the Cited Mark, and (iii) the similarity of the goods and the channels of trade are sufficiently distinct to obviate any confusion. In light of these differences, no likelihood of confusion exists between Applicant’s use of MYHERO and the Cited Mark.

1. Applicant’s Mark and the Cited Mark Must be Analyzed in Their Entireties.

When analyzing the similarity of the marks, you must compare the marks in their entirety and all components of the marks must be accorded appropriate weight, as it is the commercial impression created by the marks, considered as a whole, which is most important.

See Opryland USS, Inc. v. Great American Music Show, 970 F.2d 847, 23 USPQ2d 1471 (Fed. Cir. 1992); In re National Data Corp., 753 F.2d 1056, 224 USPQ 749 (Fed. Cir. 1985) (“likelihood of confusion cannot be predicated on dissection of a mark, that is, on only part of a mark.”); Franklin Mint Corp. v. Master Mfg. Co., 667 F.2d 1006, 1007, 212 USPQ 233 (CCPA 1981) (“It is axiomatic that a mark should not be dissected and considered piecemeal; rather, it must be considered as a whole in determining likelihood of confusion.”). The Examining Attorney has dissected the Applicant’s mark and given greater weight to the word “hero” in making the likelihood of confusion determination. By disregarding the “my” component of Applicant’s mark, the Examining Attorney has inappropriately changed the Applicant’s mark.

The commercial impression of the Applicant’s mark draws significant contribution from its entire form. Each of the components of Applicant’s mark, “my” and “hero,” contribute significantly to the impression created by the Applicant’s mark. The public will perceive the entirety of the Applicant’s mark, therefore, that is what must be compared to the Cited Mark. Applicant’s mark is a completely new word, MYHERO, whereas the Cited Mark is the word, HERO. When the Applicant’s mark and the Cited Mark are viewed in their entireties, the marks are distinguishable in their commercial impressions, as further detailed below. Therefore, when the Applicant’s mark is viewed in its entirety, consumers are not likely to be confused as to the source of goods represented by the Applicant’s mark and the Cited Mark.

2. Applicant’s Mark and the Cited Mark Differ in Sight, Sound and Appearance.

There is a strong distinction between Applicant’s mark and the Cited Mark in sight, sound and appearance. The Applicant’s mark consists of a decidedly different first term than the Cited Mark. Consumers are much more inclined to focus on the first word, prefix or syllable in any trademark. See Palm Bay Imps., Inc. v. Veuve Clicquot Ponsardin Maison Fondée En 1772, 396 F. 3d 1369, 1372, 73 USPQ2d 1689, 1692 (Fed. Cir. 2005); see also Presto Prods., Inc. v. Nice-Pak Prods., Inc., 9 USPQ2d 1895, 1897 (TTAB 1988) (it is often the first part of a mark which is most likely to be impressed upon the mind of a purchaser and remembered” when making purchasing decisions). As the first part of Applicant’s mark is likely to be impressed on the minds of the consumer and it is completely different than the Cited Mark, confusion with the Cited Mark is unlikely.

Additionally, the mere presence of a term in a mark does not by this fact alone create a likelihood of confusion with a registered mark. Colgate-Palmolive Co. v. Carter-Wallace, Inc., 432 F.2d 1400, 1403 (CCPA 1970) (holding PEAK PERIOD not to be confusingly similar to PEAK). Applicant’s mark is a combination of two distinct words, “my” and “hero,” that are grouped together to form one completely new word “myhero” whereas the Cited Mark is the sole word “hero.” The addition of the word “my” to “hero” and the creation of a new word breaks up a direct comparison between the marks and eliminates the potential for a likelihood of confusion.

The Applicant’s mark and the Cited Mark are also orally different. Applicant’s mark is three syllables and the Cited Mark is two syllables. The Applicant’s mark has a different cadence when spoken. Applicant’s mark is pronounced as two words “my” and “hero” whereas the Cited Mark is only one word “hero.” The Applicant’s mark begins with the sound “m•” and the Cited Mark begins with the sound “h•.” The emphasis in Applicant’s mark is on the first

syllable “my” and the Cited Mark does not include this sound. Accordingly, the Applicant’s mark and the Cited Mark do not sound similar and therefore confusion is unlikely.

Due to the Applicant’s mark having a different look, sound and appearance than the Cited Mark, the Applicant’s mark is not likely to create confusion with the Cited Mark.

3. Applicant’s Mark and the Cited Mark Create Different Commercial Impressions.

The Applicant’s mark and the Cited Mark create separate and distinct commercial impressions. The mere fact that the Applicant’s mark contains a term that composes the Cited Mark does not automatically justify a conclusion that the overall commercial impressions created by the marks as a whole are confusingly similar. See Conde Nast Publications, Inc., v. Miss Quality, Inc., 507 F.2d 1404, 1407 (CCPA 1975) (holding COUNTRY VOGUES not to be confusingly similar to VOGUE); In re Ferrero, 479 F.2d 1395, 1397 (CCPA 1973) (holding TIC TAC not to be confusingly similar to TIC TAC TOE); Plus Products v. General Mills, Inc., 188 U.S.P.Q. 520, 522 (TTAB 1975) (holding PROTEIN PLUS not to be confusingly similar to PLUS); In re Merchandising Motivation, Inc., 184 U.S.P.Q. 364, 367 (TTAB 1974) (holding MMI MENSWEAR not to be confusingly similar to MEN’S WEAR).

The test is not whether the marks can be distinguished when subjected to a side-by-side comparison, but rather whether the marks are sufficiently similar in terms of their overall commercial impressions that confusion as to the source of the goods or services offered under the respective marks is likely to result. H.D. Lee Co. v. Maidenform Inc., 87 USPQ2d 1715 (TTAB 2008) (holding that ONE FAB FIT is sufficiently visually and orally different from ONE TRUE FIT to create a different commercial impression; see also Shen Mfg. Co. v. Ritz Hotel, Ltd., 393 F.3d 1238, 73 USPQ2d 1350 (Fed Cir 2004) (RITZ and THE RITZ KIDS create different commercial impressions)).

In addition to the visual and oral differences discussed above, the meanings of the two marks are sufficiently distinct to create different commercial impressions. In the Applicant’s mark, the first syllable “MY” conveys a deep sense of personalization and customization for the consumer. Applicant’s mark communicates the understanding that the goods, i.e. anti-aging serum, are uniquely tailored to the consumer’s individual beauty needs. As such, the impression imposed on the consumer is that the anti-aging serum sold under Applicant’s mark is the consumer’s personal hero as its anti-aging effects are crafted and personalized for that particular consumer. The Applicant’s mark conjures up images of a savior rescuing the consumer’s face from the harsh reality of aging.

The Cited Mark is solely the word “hero.” The term “hero” is defined as (a) a mythological or legendary figure often of divine descent endowed with great strength or ability, (b) an illustrious warrior, (c) a man admired for his achievements and noble qualities, (d) one who shows great courage, (e) the principal male character in a literary or dramatic work, or (f) the central figure in an event, period, or movement. See <http://www.merriam-webster.com/> accessed on June 6, 2011(attached as Exhibit A). The Cited Mark creates the commercial impression that the men’s cologne and after shave is of the type that would be worn by a person

of great strength or ability who is admired for his achievements and qualities, a warrior or any other person of the type included in the definition of “hero.” The Cited Mark encourages the consumer to wear the men’s cologne and after shave to be like or emulate a hero. When viewing the cologne and after shave represented by the Cited Mark, the consumer will conjure up images of himself as a hero. The Cited Mark does not convey the meaning that its cologne and after shave are specially tailored or personalized for the consumer. Instead, it creates the commercial impression that if you want to have the smell, prestige or aura of a man identified as a “hero,” wear this cologne or use this after shave. The Applicant’s mark and the Cited Mark evoke very different images in the minds of the consumer and therefore convey different commercial impressions. Thus, Applicant’s mark does not create a likelihood of confusion with the Cited Mark.

4. The Nature of Goods Identified by MYHERO is Dissimilar to the Goods Identified by the Cited Mark.

The Applicant’s goods identified by MYHERO are easily distinguishable from the goods identified by the Cited Mark as they differ in nature, use and function. It is well established that the nature and scope of goods must be determined on the goods set forth in the application or registration. See Hewlett-Packard Co. v. Packard Press Inc., 281 F.3d 1261, 62 USPQ2d 1001 (Fed. Cir. 2002); J&J Snack Foods Corp. v. McDonald’s Corp. 932 F.2d 1460, 18 USPQ2d 1889 (Fed. Cir. 1991).

The Applicant’s goods are identified in its application as non-medicated anti-aging serum. The Cited Mark’s goods are identified in its registration as men’s cologne and after shave. The Applicant’s mark is used for goods that are applied to specific locations on a consumer’s face to counter the effects of aging, specifically near the eyes and forehead. The Applicant’s goods tone and moisturize the skin. The goods represented by the Cited Mark are men’s cologne applied to various parts of the body to create a pleasurable fragrance for a limited period of time and after shave applied by men to reduce the burning and stinging associated with shaving. The goods represented by the Applicant’s mark are not used for a pleasurable fragrance or to reduce the stinging of shaving. The goods represented by the Cited Mark do not firm, tone or moisturize the skin. Accordingly, the goods identified by these marks have distinct uses and therefore are not sufficiently related to cause a likelihood of confusion.

5. The Customers for Applicant’s Goods and the Customers of the Cited Mark are Different and Would Not Expect the Goods to Emanate from the Same Source.

The goods identified by the Applicant’s mark and the Cited Mark are not marketed to the same customer. When the goods of the parties are not marketed in a way that they would be encountered by the same consumers or give the incorrect assumption that they come from the same source, then, even if the marks are identical (which is not the case here), confusion is unlikely. See Quartz Radiation Corp. v. Comm/Scope Co., 1 USPQ 2d 1668 (TTAB 1986) (QR for coaxial cable held not confusingly similar to QR for various products (e.g., lamps, tubes) related to the photocopying field).

Applicant's goods are directed to reversing the signs of aging and, therefore, are marketed predominately to woman. The goods identified under the Cited Mark are directed to men as the goods are specifically identified as "men's" cologne and after shave. A consumer looking to reverse the signs of aging would not be looking for cologne or after shave to achieve the desired anti-aging result. And, a customer looking to smell good and stop the burning from shaving would not look at anti-aging serum.

To support the claim that the goods represented by the marks emanate from the same source, the Examining Attorney provided evidence of third party registrations with long lists of goods that included cologne, after shave and serums. The Trademark Trial and Appeal Board, however, has given little weight, if any, to third party registrations containing a long laundry-list of products to support the claim that the goods emanate from the same source. See In re Mucky Duck Mustard Co., Inc., 6 U.S.P.Q.2d 1467, 1470 n. 6 (TTAB 1988); In re Tomberlin Prod. Group, LLC, Serial No. 78734308 (T.T.A.B. November 30, 2007) (non-precedential), n. 1. Therefore, the cited registrations should be accorded very little weight in supporting a claim that the goods emanate from the same source.

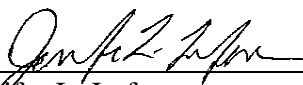
Additionally, the goods in the Applicant's mark are solely "non-medicated anti-aging serum" and goods in the Cited Mark are solely "men's cologne and after shave." The goods are not a laundry-list of goods but rather very specific goods intended for very different purposes. Customers searching for anti-aging serum would not likely believe that the Applicant's goods emanate from the same source as the goods represented by the Cited Mark. Because the Applicant's specifically identified goods are not commercially or closely related to the specific goods represented by the Cited Mark, confusion as to the source of the goods is unlikely.

III. Conclusion

Because the Applicant's mark, when considered in its entirety, is different in sight, sound and appearance and creates a different commercial impression from the Cited Mark, the goods represented by the Applicant's mark are dissimilar to the goods represented by the Cited Mark, and the intended customers are not likely to believe that the Applicant's good emanate from the same source as goods represented by the Cited Mark, there is no likelihood of confusion between MYHERO and the Cited Mark.

Reconsideration of the Application is respectfully requested. It is submitted that the present Application is in condition for publication, and such action is requested.

DATED: June 10, 2011.

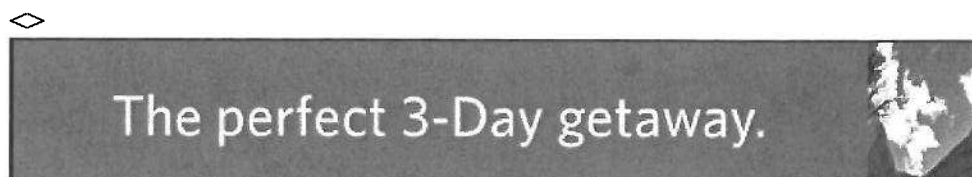


Jennifer L. Lefere
Hool Law Group, PLC
2398 E. Camelback Road, Suite 1020
Phoenix, AZ 85016
(602) 852-5580

EXHIBIT A
MERRIAM-WEBSTER DEFINITION



m-w.com



Word Games

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hero

Popularity

6 ENTRIES FOUND:

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Hero (noun)

Hero (biographical name)

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he·ro *noun* \ˈhīr-(,)ō*plural* **he·roes****Definition of HERO**

1 a : a mythological or legendary figure often of divine descent endowed with great strength or ability

b : an illustrious warrior

c : a man admired for his achievements and noble qualities

d : one who shows great courage

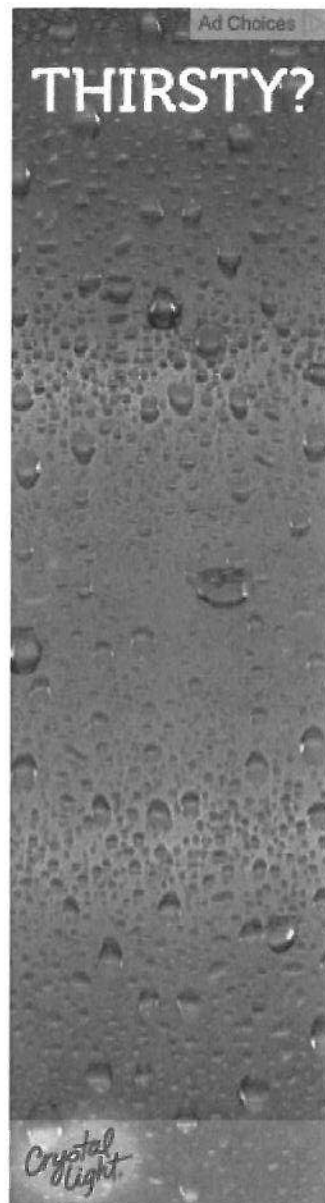
2 a : the principal male character in a literary or dramatic work

b : the central figure in an event, period, or movement

3 plural usually he·ros : SUBMARINE 2

4 : an object of extreme admiration and devotion : IDOL

Top 10 Spelling Bee Winning Words



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For iPhone & iPad *New!*



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🔍 See hero defined for English-language learners »
See hero defined for kids »

Examples of HERO

He returned from the war a national *hero*.

the *hero* of a rescue

She was a *hero* for standing up to the government.

His father has always been his *hero*.

He has always been a *hero* to his son.

A motto of his *hero*, Thomas Edison, is inscribed on a favorite sweatshirt : "To invent you need a good imagination and a pile of junk." —Britt Robson, *Mother Jones*, May/June 2008

[+] more

Origin of HERO

Latin *heros*, from Greek *hērōs*

First Known Use: 14th century

Related to HERO

Synonyms: god, idol, icon (*also* ikon)

[+] more

Other Mythology and Folklore Terms

elysian, fay, muse, nimbus, phoenix

Rhymes with HERO

zero

Britannica.com

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Exhibit 10





Exhibit 11

**Import Alert 66-38**

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(Note: This import alert represents the Agency's current guidance to FDA field personnel regarding manufacturer(s) and/or products(s) at issue. It does not create or confer any rights for or on any party and does not operate to bind FDA or the public).

Import Alert # 66-38

Published Date: 01/14/2014

Type: DWPE with Surveillance

Import Alert Name:

"Skin Care Products Labeled As Anti-Aging Creams"

Reason for Alert:

There are numerous skin care products on the market with exaggerated "anti aging" claims which cause the consumer to believe they are unapproved new drugs. Examples of such claims are that the products "counteract," "retard," or "control" the aging process. Claims that the product will "rejuvenate," "repair," or "restructure" the skin may also be drug claims. A claim that the product will absorb and expand, exerting upward pressure to "lift" wrinkles upward" is a claim for an inner structural change. Such claims usually cause a product to be a drug.

Between April 17 and June 17, 1987, Regulatory Letters were sent to several manufacturers of skin care products making these types of claims. By letter of March 24, 1988, the Associate Commissioner for Regulatory Affairs informed manufacturers that "Beginning 30 days after the date of this letter, any products found to be in substantial violation of the drug and misbranding provisions of the act may be subject to regulatory action without prior notice."

This Import Alert (IA#66-38), originally issued on June 8, 1988, listed those manufacturers that had received Regulatory Letters in the Yellow List. Since then additional manufacturers have been sent Regulatory Letters. The Yellow List now includes those manufacturers that FDA believes may be importing these skin care products with drug claims.

The Yellow List also identified those firms that FDA believes may be manufacturers or shippers of these products.

Guidance:

All entries of skin care products imported by the firms or manufactured/shipped by the firms on the Yellow List should continue to be checked for drug claims until a district is convinced the firm's products are in compliance.

Surveillance of entries of skin care products from other importers is also indicated.

Product Description:

Skin Care Products

Charge:

"The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be a new drug without an effective new drug application (NDA) as required by Section 505(a)."

OASIS Charge Code - UNAPPROVED

Red - Firms, countries and/or products that are subject to detention without physical examination of the product identified in the criteria of the alert

Yellow - List of firms and their products subject to intensified surveillance; or firms that may have satisfied GMP issues of concern, but the nature of violations may warrant further field examinations of individual entries and/or additional analyses (a.k.a. Yellow List)

Green - Firms are excluded from the criteria of the alert

Go to [Red List](#) [Yellow List](#)

List of firms and their products subject to Detention without Physical Examination (DWPE) under this Import Alert (a.k.a. Red List)

CANADA

Inventures Technologies Inc.

670 Wilsey Rd , Fredericton, Nb CANADA

	Date Publ
53 L - - 06 Moisturizing (Skin Care Preparations) Desc:Antioxidant Pomegranate Night Serum	Date
53 L - - 06 Moisturizing (Skin Care Preparations) Desc:Anti-Aging Oxygen Booster Serum	Date
53 L - - 07 Night (Skin Care Preparations) Desc:Antioxidant Pomegranate Night Serum	Date
53 L - - 99 Other Skin Care Preparations, N.E.C. Desc:Antioxidant Pomegranate Night Serum	Date
53 L - - 99 Other Skin Care Preparations, N.E.C. Desc:Anti-Aging Oxygen Booster Serum	Date
66 V - - 99 Miscellaneous Patent Medicines, Etc. Desc:Anti-Aging Oxygen Booster Serum	Date
66 V - - 99 Miscellaneous Patent Medicines, Etc. Desc:Antioxidant Pomegranate Night Serum	Date

KOREA, REPUBLIC OF (SOUTH)

Rebom Cosmetics Co Ltd

Myodong 442 48 , Seoul, Seoul KOREA, REPUBLIC OF (SOUTH)

	Date Publ
53 L - - 06 Moisturizing (Skin Care Preparations) Desc:Tripple Crown BB Cream	Date
53 L - - 99 Other Skin Care Preparations, N.E.C. Desc:Tripple Crown BB Cream	Date
66 V - - 99 Miscellaneous Patent Medicines, Etc. Desc:Tripple Crown BB Cream	Date

List of firms and their products subject to intensified surveillance; or firms that may have satisfied GMP issues of concern, but the nature of violations may warrant further field examinations of individual entries and/or additional analyses (a.k.a. Yellow List)

AUSTRALIA

Valeant Pharmaceut

3 Rider Blvd , Rhodes, AUSTRALIA

	Date Publ
66 P - - 99 Ultraviolet Screen N.E.C. Desc:Invisible Zinc; ESP 50 ml	Date
66 P - - 99 Ultraviolet Screen N.E.C. Desc:Invisible Zinc Body Screen	Date
66 P - - 99 Ultraviolet Screen N.E.C. Desc:Invisible Zinc Tinted Daywear Light 50 G	Date

BRAZIL

Claude Bergere Cosmetics

Av Tambore 827 , Sao Paulo, BRAZIL

	Date Publ
53 L - - -- Skin Care Prep	Date
66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date

CANADA

C.E. Jamieson & Company Ltd 2051 Ambassador Drive , Windsor, ON CANADA 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc. Notes:A-retinol anti-aging moisturizing complex	Date Publi Date Date
Jeneve Cosmetics Unknown Street , Richmond, BC CANADA 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
Mira Linder 108 Avenue Rd , Toronto, ON CANADA 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc. Notes:Night Corrector Regenerating Cream (12/18/1991)	Date Publi Date Date
Nutra Reaserch Int'L , Ltd 11911 Machrina Way , Richmond, BC CANADA 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
SRL/Skin Research Laboratories Unknown Street , Toronto, ON CANADA 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc. Notes:A-Retinol Anti-aging Moisturizing Complex	Date Publi Date Date
Sum Spec Canada Unknown Street , Burnaby, BC CANADA 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc. Notes:Retinol (Anti-aging cream)	Date Publi Date Date

COSTA RICA

Laboratorios Carreras S A 200 Norte y 125 Este del Joron , Apdo 7785 , Desamparados, San Jose COSTA RICA 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc. Notes:5/15/1990	Date Publi Date Date
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DENMARK

Fleur de Sante Unknown Street , Unknown, DENMARK 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc. Notes:Skin renew products	Date Publi Date Date
--	---------------------------------------

FRANCE

Arnaud Laboratories SA 124, Bd de Verdun , Courbevoie Cedex , Courbevoir Paris, FRANCE 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
Clarins 13 Rue Madeleine Michelis , Neuilly Sur Seine, FRANCE 53 L - - -- Skin Care Prep	Date Publi Date

Notes:Facial Cream 66 V - - 99 Miscellaneous Patent Medicines, Etc. Notes:Facial Cream	Date
Ella Bache 87 Rue Marceau , Montreuil, FRANCE 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
Guerlain Western Hemisphere Corporation, Ltd. P.O. Box 52 , Freeport, FRANCE 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc. Notes:9/12/1994	Date Publi Date Date
Helena Rubinstein PBI Parfums Beaute Int BP 433 , Rungis Cedex, FRANCE 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
Jean D'Estrees Paris Produits De Beaute 29, Rue D'Astorg , Paris,, FRANCE 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
Julian Jill Ave La Martine 86 , BP 100, 22 Z.A. De L'Agavon , Les Pennes Mirabeau Cedex, FRANCE 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
L'Oreal 11 Rue Klock , Clichy, FRANCE 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
Laboratoire De Narhex Unknown Street , Paris, FRANCE 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
Laboratories Dr. N.G. Payot 10, Rue De Castiglione , Paris, FRANCE 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc. Notes:AUthentic (Payot) Products	Date Publi Date Date
Matis S.A. 5, Rue Scribe , Paris, FRANCE 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
Parfums Lancome 14 Rue Royale , Paris, FRANCE 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
S.A. Laboratories B.L.C. Thalgo Cosmetic Unknown , Roquebrune, FRANCE	Date Publi

53 L - - - Skin Care Prep	Date
66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date
Notes:Ogive; Complex Liposomes Anti-Wrinkle Extract (Renovatrices)	

Sothys	Date Pub
14 R De L'Hotel De Ville , Brive La Gaillarde, FRANCE	
53 L - - - Skin Care Prep	Date
66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date
Notes:Sothys-formule Exygenate	

Stendhal Paris	Date Pub
62 Avenue D'Iena , Paris, FRANCE	
53 L - - - Skin Care Prep	Date
66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date

Yves Rocher	Date Pub
56800 , Ploermel, FRANCE	
53 L - - - Skin Care Prep	Date
66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date

GERMANY

Dr Babor Gmbh P Co	Date Pub
Neuenhofstr 180 , Postfach 207 , Aachen, GERMANY	
53 L - - - Skin Care Prep	Date
66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date

Helena Rubinstein Inc	Date Pub
Albert Einstein Strasse 1-3 , Etkrath Unterfeldhauf De, GERMANY	
53 L - - - Skin Care Prep	Date
66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date
Notes:Skin Life products	

Korber Ag	Date Pub
Kampchausse 8-32 , Hamburg, GERMANY	
53 L - - - Skin Care Prep	Date
66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date

HONG KONG

Narhex Ltd.	Date Pub
Unknown Street , Hong Kong, HONG KONG	
53 L - - - Skin Care Prep	Date
66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date

ISRAEL

Paloma Dead Sea, Ltd.	Date Pub
38900 Caesarea , Caesarea, IL-NOTA ISRAEL	
53 K - - - Shaving Prep	Date
53 L - - - Skin Care Prep	Date

ITALY

Profumi E Cosmetici Italiani	Date Pub
Via Aurelia KM 300 Ladispoli , Rome, ITALY	
53 L - - - Skin Care Prep	Date
66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date
Notes:10/30/1990	

Terme di Saturnia	Date Pub
Unknown Street , Milano, ITALY	

53 L - - -- Skin Care Prep
66 V - - 99 Miscellaneous Patent Medicines, Etc.

Date
Date

JAPAN

Lo Shi Ltd.
Unknown Street , Unknown, JAPAN

Date Pub

53 L - - -- Skin Care Prep
66 V - - 99 Miscellaneous Patent Medicines, Etc.
Notes:LoShi 24 Gold Cosmetics

Date
Date

KOREA, REPUBLIC OF (SOUTH)

AMORE PACIFIC CORPORATION
181, 2GA HANGANG-RO , YONGSAN-GU, Kr-11 KOREA, REPUBLIC OF (SOUTH)

Date Pub

53 L - - -- Skin Care Prep

Date

SPAIN

BelNature Cosmetics International
San Bernardo 97-99 , Madrid, SPAIN

Date Pub

53 L - - -- Skin Care Prep
66 V - - 99 Miscellaneous Patent Medicines, Etc.

Date
Date

Chantelet, S.A. Laboratori
Santa Leonor, 48 , Madrid, SPAIN

Date Pub

53 L - - -- Skin Care Prep
66 V - - 99 Miscellaneous Patent Medicines, Etc.

Date
Date

Germaine De Capuccini
Mallorea 81, Bajos , Barcelona, SPAIN

Date Pub

53 L - - -- Skin Care Prep
66 V - - 99 Miscellaneous Patent Medicines, Etc.
Notes:Royal Jelly Milk/Royal Jelly Mask/Royal Jelly Cream/Elastin Nourishing Cream

Date
Date

Idesco Investigacion Y Desarrollo De Cosméticos Sa
C/Costa Brava, 30 , Barcelona, SPAIN

Date Pub

53 L - - -- Skin Care Prep
66 V - - 99 Miscellaneous Patent Medicines, Etc.

Date
Date

Lendan Iberica, S.A.
Unknown Street , Barcelona, SPAIN

Date Pub

53 L - - -- Skin Care Prep
66 V - - 99 Miscellaneous Patent Medicines, Etc.

Date
Date

SWITZERLAND

Gerda Spillmann International
Neugasse 6 , Zurich, SWITZERLAND

Date Pub

53 L - - -- Skin Care Prep
66 V - - 99 Miscellaneous Patent Medicines, Etc.
Notes:5/15/1990

Date
Date

Laboratoire Sintyl S.A.
23 Route des jeunes - Carouge , Geneva, SWITZERLAND

Date Pub

53 L - - -- Skin Care Prep
66 V - - 99 Miscellaneous Patent Medicines, Etc.

Date
Date

Paul Scerri S.A.
14, Chemin Du Pre-Fleuri , Plan-Les-Ouates, Geneva SWITZERLAND

Date Pub

53 L - - -- Skin Care Prep
66 V - - 99 Miscellaneous Patent Medicines, Etc.

Date
Date

UNITED STATES

Adrien Arpel 521 5th Ave , New York, NY 10175-0003 UNITED STATES 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
Aesthetics Complete Inc. 411e E Lancaster Ave , Wayne, PA 19087-4202 UNITED STATES 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
Almay Inc 625 Madison Ave , New York, NY 10022-1801 UNITED STATES 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
Avon Products Inc 777 3rd Ave , New York, NY 10017-1401 UNITED STATES 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
Beauty Center of Palm Beach 5612 S Dixie Hwy , West Palm Beach, FL 33405-3658 UNITED STATES 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
BelNature Cosmetics, Inc. 1850 Coral Way , Miami, FL 33145-2731 UNITED STATES 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
Bio-Therapeutic Computers Inc 2244 - 1st Ave South , Seattle, WA 98134 UNITED STATES 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
Botanical Garden 800 E Cypress Creek Rd Ste 304 , Fort Lauderdale, FL 33334-3512 UNITED STATES 53 L - - -- Skin Care Prep 66 V - - -- Patent Medicines, Etc	Date Publi Date Date
Carisam Samuel Meisel, Inc. 2707 N Rolling Rd Ste 120 , Baltimore, MD 21244-2157 UNITED STATES 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc. Notes:Evolution Skin Care Products (9/12/1994)	Date Publi Date Date
Chanel Inc 9 W 57th St Fl 9 , New York, NY 10019-2602 UNITED STATES 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
Chesebrough-Ponds USA 33 Benedict Pl , Greenwich, CT 06830-5339 UNITED STATES 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
Christian Dior Perfumes	Date Publi

9 W 57th St Fl 9 , New York, NY 10019-2602 UNITED STATES

53 L - - -- Skin Care Prep

Date

66 V - - 99 Miscellaneous Patent Medicines, Etc.

Date

Clarins Usa, Inc.**Date Pub****135 E 57th St , New York, NY 10022-2050 UNITED STATES**

53 L - - -- Skin Care Prep

Date

66 V - - 99 Miscellaneous Patent Medicines, Etc.

Date

Cosmair Inc**Date Pub****575 5th Ave , New York, NY 10017-2422 UNITED STATES**

53 L - - -- Skin Care Prep

Date

66 V - - 99 Miscellaneous Patent Medicines, Etc.

Date

Cosmair Inc**Date Pub****575 5th Ave , New York, NY 10017-2422 UNITED STATES**

53 L - - -- Skin Care Prep

Date

66 V - - 99 Miscellaneous Patent Medicines, Etc.

Date

Coty Company**Date Pub****Unknown Street , New York, NY 10017 UNITED STATES**

53 L - - -- Skin Care Prep

Date

66 V - - 99 Miscellaneous Patent Medicines, Etc.

Date

Elizabeth Arden**Date Pub****2634 Broadwayen , New York, NY 10025 UNITED STATES**

53 L - - -- Skin Care Prep

Date

66 V - - 99 Miscellaneous Patent Medicines, Etc.

Date

Estee Lauder Inc**Date Pub****767 5th Ave Fl 47th , New York, NY 10153-0023 UNITED STATES**

53 L - - -- Skin Care Prep

Date

66 V - - 99 Miscellaneous Patent Medicines, Etc.

Date

Frances Denney Inc.**Date Pub****437 Madison Ave , New York, NY 10022-7001 UNITED STATES**

53 L - - -- Skin Care Prep

Date

66 V - - 99 Miscellaneous Patent Medicines, Etc.

Date

Gadol Distributors**Date Pub****2383 Collins Ave , Miami Beach, FL 33139-1609 UNITED STATES**

53 L - - -- Skin Care Prep

Date

66 V - - 99 Miscellaneous Patent Medicines, Etc.

Date

Germaine Monteil**Date Pub****625 Madison Ave , New York, NY 10022-1801 UNITED STATES**

53 L - - -- Skin Care Prep

Date

66 V - - 99 Miscellaneous Patent Medicines, Etc.

Date

Huber Research Labs Inc Max**Date Pub****5341 Derry Ave , Agoura, CA 91301-4510 UNITED STATES**

53 L - - -- Skin Care Prep

Date

66 V - - 99 Miscellaneous Patent Medicines, Etc.

Date

Image XII International**Date Pub****8340SW 8 Street , Miami, FL 33165 UNITED STATES**

53 L - - -- Skin Care Prep

Date

66 V - - 99 Miscellaneous Patent Medicines, Etc.

Date

JENEVE Cosmetics Unknown , Blaine, WA 98230 UNITED STATES 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
La Prairie 680 5th Ave Fl 14 , New York, NY 10019-5429 UNITED STATES 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
Lendan USA 7924 Nw 66th St , Miami, FL 33166-2726 UNITED STATES 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
Matis U.S.A., Inc. 305 Kingston Ave , Daytona Beach, FL 32114-2003 UNITED STATES 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
Mira Linder 29935 North Western Hwy Appligate , Southfield, MI 48034 UNITED STATES 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc. Notes:Night Correrctor Regenerating Cream (12/18/1991)	Date Publi Date Date
Neyda E. Avila 1645 S Miami Ave , Miami, FL 33129-1103 UNITED STATES 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
Noblesse International Ltd. 1129 Northern Blvd , Manhasset, NY 11030-3022 UNITED STATES 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
Orlane,Inc 16 E 52nd St , New York, NY 10022-5306 UNITED STATES 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
Parbel 2305 Nw 107th Ave , Doral, FL 33172-2182 UNITED STATES 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
Rachel (Perry) Inc 9111 Mason Ave , Chatsworth, CA 91311-6110 UNITED STATES 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
Revlon Inc 767 5th Ave , New York, NY 10153-0023 UNITED STATES 53 L - - -- Skin Care Prep 66 V - - 99 Miscellaneous Patent Medicines, Etc.	Date Publi Date Date
Revlon Intl Inc 625 Madison Ave , New York, NY 10022-1801 UNITED STATES 53 L - - -- Skin Care Prep	Date Publi Date

66 V - - 99 Miscellaneous Patent Medicines, Etc.

Date

Sanofi Beaute, Inc

Date Pub

40 E 52nd St , New York, NY 10022-5911 UNITED STATES

53 L - - -- Skin Care Prep

Date

66 V - - 99 Miscellaneous Patent Medicines, Etc.

Date

Shiseido Cosmetics America

Date Pub

900 3rd Ave , New York, NY 10022-4728 UNITED STATES

53 L - - -- Skin Care Prep

Date

66 V - - 99 Miscellaneous Patent Medicines, Etc.

Date

Skin Culture Institute, Inc.

Date Pub

38 W 32nd St Ste 1312 , New York, NY 10001 UNITED STATES

53 L - - -- Skin Care Prep

Date

66 V - - 99 Miscellaneous Patent Medicines, Etc.

Date

Swiss Skin Care Inc

Date Pub

13401 Bel Red Rd , Bellevue, WA 98005-2322 UNITED STATES

53 L - - -- Skin Care Prep

Date

66 V - - 99 Miscellaneous Patent Medicines, Etc.

Date

The Hain Celestial Group Personal Care

Date Pub

8468 Warner Dr , Culver City, CA 90232-2429 UNITED STATES

53 L - - -- Skin Care Prep

Date

66 V - - 99 Miscellaneous Patent Medicines, Etc.

Date

Yves Rocher Usa Inc P

Date Pub

1305 Goshen Parkway , .O.Bos 2673 , West Chester, PA 19380 UNITED STATES

53 L - - -- Skin Care Prep

Date

66 V - - 99 Miscellaneous Patent Medicines, Etc.

Date

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4. <http://www.fda.gov/ForIndustry/ImportProgram/default.htm>

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Silver Spring, MD 20993
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